District Judge Benjamin H. Settle

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

ROBERT D. FARVOUR and ELAINE FARVOUR, individually and as husband and wife, Plaintiffs, v. UNITED STATES OF AMERICA, Defendant.	Case No. 18-5386-BHS UNITED STATES' DISCLOSURE OF EXPERT WITNESSES

Pursuant to Fed. R. Civ. P. 26(a)(2), and this Court's Order of May 29, 2019 (Dkt. 15), Defendant United States of America, by and through its undersigned attorneys, make the following disclosure of potential expert witnesses.

(1) Kelly R. White, M.D.
5402 47th Avenue NE
Seattle, WA 98105
Phone: (206) 525-4090

Dr. White's preliminary opinions and basis thereto, CV, listing of prior testimony, and fee schedule are attached to this document. In addition to the opinions expressed in his report, it is anticipated that Dr. White will also address any testimony or opinions offered by Plaintiffs'

UNITED STATES ATTORNEY
700 Stewart Street, Suite 5220
Seattle, Washington 98101-1271
206-553-7970

expert(s) within his areas of expertise. Dr. White may review some or all of the subsequent deposition transcripts in this matter, and the opinions of other experts or witnesses, before rendering a final opinion. The United States reserves the right for Dr. White to modify his opinions in light of any additional information that may become available. The United States also reserves the right for Dr. White to identify at a later date exhibits, if any, he may use pursuant to Fed. R. Civ. P. 26(a)(2).

(2) Richard S. Pelman, M.D.
University of Washington
Department of Urology
1959 NE Pacific Street
HSB BB 1128
Seattle, WA 98195
Phone: (206) 598-4294

Dr. Pelman's preliminary opinions and basis thereto, CV, listing of prior testimony, and fee schedule are attached to this document. In addition to the opinions expressed in his report, it is anticipated that Dr. Pelman will also address any testimony or opinions offered by Plaintiffs' expert(s) within his areas of expertise. Dr. Pelman may review some or all of the subsequent deposition transcripts in this matter, and the opinions of other experts or witnesses, before rendering a final opinion. The United States reserves the right for Dr. Pelman to modify his opinions in light of any additional information that may become available. The United States also reserves the right for Dr. Pelman to identify at a later date exhibits, if any, he may use pursuant to Fed. R. Civ. P. 26(a)(2).

(3) Erick C. West, M.A.
West Economics, Inc.
10220 N. Nevada Street, Suite 110
Spokane, WA 99218
Phone: (509) 747-5850

UNITED STATES ATTORNEY
700 Stewart Street, Suite 5220
Seattle, Washington 98101-1271
206-553-7970

Mr. West's CV, listing of prior testimony, and fee schedule are attached to this document. The United States will supplement with his report on July 30, 2019. In addition to the opinions expressed in his report, it is anticipated that Mr. West will also address any testimony or opinions offered by Plaintiffs' expert(s) within his areas of expertise. Mr. West may review some or all of the subsequent deposition transcripts in this matter, and the opinions of other experts or witnesses, before rendering a final opinion. The United States reserves the right for Mr. West to modify his opinions in light of any additional information that may become available. The United States also reserves the right for Mr. West to identify at a later date exhibits, if any, he may use pursuant to Fed. R. Civ. P. 26(a)(2).

(4) Dana Penilton, RN, BSN, CCM, CLCP
6312 SW Capitol Highway, # 418
Portland, OR 97239
Phone: (503) 701-9009

Ms. Penilton's life care plan and basis thereto, medical chronology, CV, fee schedule and listing of prior testimony are attached to this document. In addition to the opinions expressed in her life care plan, it is anticipated that Ms. Penilton will also address any testimony or opinions offered by Plaintiffs' expert(s) within her areas of expertise. Ms. Penilton may review some or all of the subsequent deposition transcripts in this matter, and the opinions of other experts or witnesses, before rendering a final opinion. The United States reserves the right for Ms. Penilton to modify her opinions in light of any additional information that may become available. The United States also reserves the right for Ms. Penilton to identify at a later date exhibits, if any, she may use pursuant to Fed. R. Civ. P. 26(a)(2).

(5) The United States reserves the right to supplement this disclosure as developments warrant, and to add rebuttal experts as needed within the time frame allowed by the rules.

UNITED STATES ATTORNEY
700 Stewart Street, Suite 5220
Seattle, Washington 98101-1271
206-553-7970

(6) The United States reserves the right to call any person disclosed as an expert by Plaintiffs under Fed. R. Civ. P. 26.

(7) The United States reserves the right to call any and all persons in the United States' Initial Disclosures, Plaintiffs' Initial Disclosures, and supplements thereto, to offer other fact and/or opinion testimony on technical issues, either by declaration or by live testimony, based on particularized knowledge, skill, experience, training, or education as provided under the federal rules.

(8) The United States reserves the right to call any and all of Plaintiffs' providers for physical health and mental health who have been disclosed through discovery to the extent that they may qualify as experts as provided under the federal rules.

DATED this 29th day of July, 2019.

Respectfully submitted,

BRIAN T. MORAN
United States Attorney

s/ Whitney Passmore
WHITNEY PASSMORE, FLA #91922
MATT WALDROP, GA # 349571
Assistant United States Attorneys
United States Attorney's Office
700 Stewart Street, Suite 5220
Seattle, Washington 98101-1271
Phone: 206-553-7970
E-mail: james.waldrop@usdoj.gov
E-mail: whitney.passmore@usdoj.gov

Attorneys for the United States of America

CERTIFICATE OF SERVICE

I hereby certify that I am an employee in the Office of the United States Attorney for the Western District of Washington and a person of such age and discretion as to be competent to serve papers;

I further certify that I have served the foregoing on the attorney(s) of record for the plaintiffs via e-mail. It is further certified that on July 29, 2019, I electronically filed the United States' Disclosure of Expert Witnesses using the CM/ECF system, which will send notification of such filing to the following CM/ECF participant(s):

James L. Holman jlh@theholmanlawfirm.com:

Dated this 29th day of July, 2019.

s/ *Matt Waldrop*
Assistant U.S. Attorney
United States Attorney's Office
700 Stewart Street, Suite 5220
Seattle, Washington 98101-1271
Phone: 206-553-7970
E-mail: matt.waldrop@usdoj.gov

July 29, 2019

Matt Waldrop
Assistant United States Attorney
United States Attorney's Office
Western District of Washington
700 Stewart Street, Suite 5200
Seattle, WA 98101

RE: Farvour vs United States, No. 3:18-cv-05386-BHS

Mr. Waldrop,

I am a Urologist who is Board Certified and Recertified with a current Certificate from the American Board of Urology (Expiration date 2028). I am licensed to practice medicine in the State of Washington and have an inactive license in Massachusetts. I graduated from the University Of Washington School Of Medicine in 1979. I then completed General Surgery and Urology Training at Boston University Medical Center and Affiliated Hospitals from 1979 to 1985. My CV details my employment and educational history and is attached as Exhibit A.

I have been a clinical faculty member in the Department of Urology at the University of Washington since 1987. Currently, I am employed with the University of Washington, UW Physicians, as a Clinical Professor of Urology and by the University of Washington Department of Urology practicing at the UW Physicians Eastside Specialty Center in Bellevue, Washington.

In formulating my opinions in this case, I have reviewed the following medical records and materials of Robert Farvour:

1) VA records
2) Outside Physicians (GI group Longview WA and Longview Urology)
3) Hospital Records from St John Medical Center
4) Attestation of Dr. Michael Brawer
5) Attestation of Dr. Peter McGough
6) Depositions of Anjal Ohri MD, Tracy Gutman MD, Eileen Horner MD and Jesse Talalotu, MD
7) Deposition of Robert Farvour
8) Deposition of Elaine Farvour

I am familiar with the applicable standard of care concerning the treatment, care and diagnosis of prostate cancer. It is my belief, with a reasonable degree of medical certainty, that Mr. Farvour received the appropriate standard of care through the VA system and its primary care physicians, Drs. Ohri, Gutman, Horner and Talalotu.

Mr. Farvour had low and stable prostate-specific antigen (PSA) values from 2001 through 2004. Specifically, Mr. Farvour had a PSA of 1.9 on August 3, 2001, a PSA of 1.9 on February 12, 2002, and a PSA of 1.8 on March 12, 2004. In 2006, Mr. Farvour's PSA was 1.6, which was lower, or stable with lab variation, from his prior PSA values.

A PSA of 2.3 was recorded for Mr. Farvour on September 22, 2008, which is an acceptable PSA increase over the time period. On September 23, 2009, Mr. Farvour's PSA was stable at 2.6. Mr. Farvour's next PSA result was 2.9 on October 12, 2011, which was again an acceptable increase for the 2009-2011 time period.

In early 2017, Mr. Farvour developed urinary retention and underwent a transurethral resection of the prostate (TURP) to relieve his benign prostatic obstruction causing bladder outlet obstruction. The outside consulting urologist did not suggest a prostate biopsy to rule out prostate cancer or a PSA before undertaking the TURP. A biopsy or PSA test would not have altered the course of Mr. Farvour's disease or its treatment. The prostate pathology from the TURP surgery returned with high grade high volume prostate cancer and Mr. Farvour's PSA was noted to be 284.5. Subsequent evaluation for metastasis was positive.

No PSA had been obtained for Mr. Farvour from October 12, 2011 until the 2017 PSA testing. This was not an oversight or negligence by the VA physicians. Though the Plaintiffs' experts have argued that the standard of care was breached, it was not. The issue was not oversight, lack of attention, or a deviation from the standard of care by the VA physicians, but rather it was their adherence to a national policy recommendation from the United States Preventive Services Task Force (USPSTF), which was issued in 2012. This policy is attached as Exhibit B.

In 2012, the USPSTF demoted the PSA blood test to a grade of D, or a "not recommended" category of test. Previously the PSA blood test had been placed as an indeterminate status by the USPSTF. The consequence of the USPSTF's recommendation to downgrade the PSA blood test to a D resulted in primary care physicians adhering to this national guidance and, accordingly, primary care physicians stopped ordering the PSA blood test. The American Academy of Family Physicians, the Internal Medicine National governing body, and the American College of Physicians all take their direction from the USPSTF.

The USPSTF convenes as a panel to evaluate screening tests, like the PSA blood test. The have evaluated PAP smears, mammography, blood sugar, colorectal cancer, lung cancer, and abdominal Aortic Aneurysm screening tests. In sum, if it is a screening test, the USPSTF will review it.

The USPSTF reviews the screening tests with regard to the benefits and harms of the screening test. In reviewing benefits, the USPSTF considers how many lives are saved by the test over control or unscreened individuals. In considering the harms of screening

tests, the USPSTF reviews the effects of the screening test AND the outcome and consequences of a positive test, *i.e.*, the corresponding treatment.

In the case of the PSA blood test, the USPSTF reviewed the potential issues and risks of false positives, the risks of the biopsy and the risks and changes to quality of life from prostate cancer treatment.

No urologist was on the USPSTF, though the panel did take testimony from urologists. In response, and consistent with the USPSTF's decision to downgrade the PSA blood test to a D, primary care physicians simply stopped ordering this screening test.

The USPSTF did not recommend that primary care physicians discuss getting a PSA test with their patients. In fact, the USPSTF specifically stated that they did not recommend offering the PSA blood test for patients, and that "physicians should not offer or order PSA screening unless they are prepared to engage in shared decision making that enables an informed choice by the patient." This is a different statement than implied by the Plaintiffs' experts. The USPSTF specifically did not suggest the PSA blood test be offered or ordered. If the PSA test was offered or ordered, only then would shared decision making between the primary care physician and the patient come into the discussion.

Similarly, patients requesting PSA screening should be provided with the opportunity to make informed choices to be screened that reflect their values about specific benefits and harms. In my review, I was unable to find any documentation that Mr. Farvour ever requested a PSA screening test.

Thus, in reviewing the USPSTF 2012 statement of policy, they did not suggest that physicians offer the PSA blood test or provide material concerning PSA testing. If the patient requested the PSA screening test, or if the physician were to offer PSA screening test, only then would it be necessary to initiate informed decision making.

The USPSTF briefly discussed Agent Orange exposure (a defoliant used in the Vietnam War), which is considered to be a risk factor for prostate cancer, although limited data existed at the time, or now, on the outcomes or effect of PSA testing and treatment for these individuals. Prostate cancer in Vietnam veterans who were exposed to Agent Orange is considered a service-connected condition by the Veterans Health Administration, which is separate from the VA's hospital staff.

Critically, the USPSTF did not make a recommendation regarding PSA screening for individuals exposed to Agent Orange. The VA physicians in this case, and their counterparts around the country, were acting within the standard of care regarding PSA testing at the time, based on the USPSTF's recommendation.

I've provided as Exhibit C an excellent summary of 4 organizations, published by the American College of Physicians, titled Screening for Prostate Cancer A Guidance Statement from the Clinical Guidelines Committee of the American College of Surgeons.

Clearly in reviewing the Summary, the 2012 USPSTF PSA policy differs considerably from the American Cancer Society (ACS) and the American Urological Association (AUA) recommendations. As Urologists, we were made aware of the USPSTF's potential recommendations well before they were published in 2012. Organized urology was able to comment and testify prior to the published final recommendation in 2012. It is highly likely that primary care physicians were also aware of the upcoming 2012 USPSTF recommendation well before the panel published its final recommendation.

The USPSTF is the organization that primary physicians, like the four doctors here, follow, not the ACS or the AUA. Thus, the opinion that Mr. Farvour should have received informed or shared decision-making from his VA providers is in conflict with the 2012 recommendation of the USPSTF.

I have practiced clinical urology since 1985. I have patients, and have seen patients who, like Mr. Farvour, had previously had PSA testing done up until 2012 and not again until May of 2018, when the USPSTF again reviewed PSA screening tests (they are mandated to review all screening tests periodically because the science behind the screening tests is dynamic), and upgraded PSA screening test for men from ages 55 to 69 to a C category. For men over 70, the USPSTF left its recommendation as a D.

In the interval from 2012 to 2018, I, as a urologist, was able to obtain PSA values on men referred for other Urological issues (voiding difficulties, blood in the urine, sexual health issues, pelvic pain, genital concerns and more). The overwhelming majority of these men had not had PSA testing done by their primary care physician.

As a urologist, I felt that PSA had value, and was very confortable in its use despite its lack of specificity for prostate cancer. As a urologist, I was in step with the urological community. We felt that the downgrading of PSA in 2012 by the USPSTF would have unfortunate consequences for men, and indeed some studies have demonstrated an increase in advanced stages of prostate cancer during the time from 2012 to 2018.

Organized urology responded to the proposed downgrading in 2012 by the USPSTF with a request to leave the test as an indeterminate rating. Expert urologists testified on behalf of PSA to the USPSTF. As I mentioned above, no urologist was on the USPSTF. A bill was introduced by US Senator Marsha Blackburn to address this issue, which would stipulate that any future USPSTF task force members include a member from the area/field that screening tests were being reviewed.

I have included as Exhibit D a response to the USPSTF from the American Association of Clinical Urologists (AACU), which I helped author as the incoming president at that time.

The potential consequences for primary care physicians of ignoring clinical guidance from the USPSTF are more than just policy related. During 2014, a document and comments from a CMS consultant were reviewed, which would have had CMS penalize primary care providers for ordering PSA testing through financial withholding of

Medicare payments. In other words, a primary care practitioner who ordered a PSA against USPSTF guidelines would have received a significant reduction in their Medicare payment.

Fortunately sufficient comments were generated in opposition, and the consulting agency's proposal was not implemented. However, concerns that insurance companies will not reimburse for tests rated lower than C by the USPSTF still exists.

It is truly unfortunate that Mr. Farvour's situation illustrates the consequences of the USPSTF downgrading of PSA during the time period where screening was not recommended. However, it is not the fault of his primary care physicians or the VA. Mr. Farvour's primary care physicians were simply following the clinical guidance that was inherent in their practice of medicine. The VA physicians and non-VA primary care physicians were in step with the recommendations regarding PSA testing that were active at that time.

PSA velocity, or change in PSA values over time, was reviewed in an excellent article in 2011, included as Exhibit E, that cast doubt on the AUA Guidelines and the National Comprehensive Cancer Network (NCCN) guidelines of the same year regarding use of PSA velocity. The article found no "evidence to support the recommendation that men with high PSA velocity should be biopsied in the absence of other indications; this measure should not be included in practice guidelines."

It is highly likely that while primary care physicians may not have read the article, the articles conclusion would have circulated among them via discussions, CME and peer to peer dialogue.

In sum, the VA and its primary care physicians practiced to the standard of care of the time in following the USPSTF guidance issued in 2012.

/s/ Richard S. Pelman, M.D.
Richard S. Pelman, MD
Clinical Professor, Department of Urology, University of Washington
AACU Urology Delegate, AMA House of Delegates
Board Member and Past President AACU
Chair, Committee on Men's Health, Washington State Urology Society

CURRICULUM VITAE

Richard Stuart Pelman, M.D.

PERSONAL HISTORY

Business Address	Department of Urology University of Washington 1959 NE Pacific Street HSB BB1128 Box 356510 Seattle, Washington 98195
Date of Birth:	October 1, 1951 Los Angeles, CA
Social Security Number:	Available upon request.
Marital Status:	Married Spouse, Sally Browning, M.D.
Children:	Alexander William Pelman Emma Rose Pelman

EDUCATION

1974	University of Washington, Seattle, Washington B.A. Zoology, Anthropology
1979	University of Washington, Seattle, Washington M.D.

RESIDENCY

1979-1982	Boston University Affiliated Hospitals Surgery Residency
1982-1985	Boston University Affiliated Hospitals Urology Residency

MEDICAL LICENSURE

Massachusetts Board of Registration in Medicine (49881) August 1982
(The Massachusetts License is Inactive)
State of Washington (22864) June 1985- current
Diplomat of the National Board of Medical Examiners, June 1980
Board Certified American Board of Urology, March 1988
Re-certification February 1998, 2008, 2018 (recertified 2015), expires 2028

FACULTY APPOINTMENTS

Clinical Professor – University of Washington
School of Medicine, Department of Urology July 2000
Clinical Associate Professor – University of Washington
School of Medicine, Department of Urology July 1992
Clinical Assistant Professor—University of Washington
School of Medicine, Department of Urology July 1989
Clinical Instructor, Department of Urology, University of Washington
School of Medicine, Department of Urology, 1989

STAFF APPOINTMENTS AND POSITIONS

Consultant – Seattle Veterans Administration Hospital
Department of Urology, Surgical Attending
Consultant to the Spinal Cord Injury Unit, Seattle Veterans
Administration Hospital 1986-1989
Chief of Surgery – Overlake Hospital Medical Center,
Bellevue, Washington September 1991-September 1993
Medical Staff Secretary Treasurer – Overlake Hospital Medical
Center, Bellevue, Washington 1994-1996, 1996-1997
Chairman Credentials Committee, Overlake Hospital Medical
Center, Bellevue, Washington 1997- December 2000
Chairman Practice Development Committee, Overlake Hospital
Medical Center, Bellevue, Washington January 2001 – Dec. 2002
Member Executive Committee, Overlake Hospital Medical Center,
Bellevue, Washington 1994 – 2002

HOSPITAL AFFILIATIONS

University of Washington Medical Center 2014-
Overlake Hospital Medical Center, Active Staff, December 1985-2014
Evergreen General Hospital, Active Staff, December 1985 -2014
Seattle Veterans Administration Hospital, Active Staff, 1986-1989
Seattle Veterans Administration Hospital Consulting Staff 1989-
Swedish Hospital, Courtesy Staff, November 1985- 2014

Swedish Medical Center/Providence Hospital, Courtesy Staff, March 1994-2014

PROFESSIONAL AFFILIATIONS

Chair, Ad Hoc Committee on Male Health, American Urological Assoc. 2009-2010, Developed concept, launched and chaired first committee for the AUA.
Member Technical Expert Panel, Evidence Based Practice Centers Program of the Agency for Healthcare Research and Quality for Guidelines for Overactive Bladder 2008-2009
Western Section Representative to UROPAC Board of Directors
Board Member Western Section Representative, American Association of Clinical Urologists Board of Directors, 3- 2008 - 9-2012,
State Society Network Chair, American Association of Clinical Urologists 9-2011 - 9-2012
President elect, American Association of Clinical Urologists 9 – 2012 – 9-2013
President, American Association of Clinical Urologists 9- 2013- 9, 2014
Immediate Past President American Association of Clinical Urologists 2014- present
American Association of Clinical Urologists Delegate to the AMA House of Delegates 2014, 2015, 2016, 2017, 2018…..2020
Member, American Medical Association
Member, King County Medical Association
Member, Northwest Urological Society, December 1986
Executive Committee, Membership Chairman 1994
Executive Committee, Exhibit Chairman 2000
Executive Committee, Secretary-Treasurer 2008
President elect 2011
President 2012
Member, Washington State Urology Society
Member at Large 1993-1995
Executive Committee Member 1993 – Present
Secretary Treasurer 1995-1997
President-Elect 1996-1998
Chair, Committee on Men's Health 1998-Present
President 1999-2000
Immediate Past President 2001-2002
Member, American Fertility Society, October 1986
Member, Seattle Surgical Society, January 1989
Member, Western Section of the American Urological Society, October 1990
Member, American Urological Association, 1991
Member, American Association of Clinical Urologists, Inc., May 1994

Board Member, University of Washington School of Medicine Alumni Association, representing class of 1979, 1996-2002.
Member, Clinical Faculty, Academic Faculty, Advisory Committee, University of Washington, Department of Urology, 1998-Present

ORGANIZATIONS

National Kidney Foundations of Washington, Member
Board of Directors and Executive Committee Member, 1987-1993

HONORS

Pfizer Scholars in Urology Award, September 1997

Listed in the "Guide to Top Doctors" from the Center for the Study of Services, Consumers' Checkbook 1999-2000. A peer referenced Survey asking 260,000 physicians in more than 50 of the largest Metropolitan areas which specialists in 30 different fields he or She would consider most desirable for care of a loved one.

Listed in the "Guide to Top Doctors" from the Center for the Study of Services, Consumers' Checkbook 2008-2009. A peer referenced Survey asking 260,000 physicians in more than 50 of the largest Metropolitan areas which specialists in 30 different fields he or She would consider most desirable for care of a loved one.

Voted one of Seattle's top physicians, chosen by their peers, Seattle Magazine, September 2000

Voted one of Seattle's top physicians for women, chosen by their peers, Seattle Magazine, September 2003

Voted one of Seattle's top physicians, chosen by their peers, Seattle Magazine, September 2004

Listed in the "Guide to Top Doctors" from the Center for the Study of Services. Consumers' Checkbook 2004-2005.

Voted one of Seattle's top physicians, chosen by their peers, Seattle Magazine, September 2005

Voted one of Seattle's top physicians, chosen by their peers, Seattle Magazine, September 2009

Voted one of Washington's top physicians, chosen by their peers, Washington Magazine, 2010

Graduation Speaker (First Alumni Guest Speaker) University of Washington Department of Anthropology June 11, 2010

Voted one of Washington's Best Doctors, chosen by their peers, Washington Magazine 2011

Selected as one of the Nation's Top Doctors, chosen by their peers, U.S. News & World Report 2011

Voted one of Seattle's Top Doctors, chosen by their peers, Seattle Met Magazine, 2015

Puget Sound Consumers Checkbook (www.checkbook.org) Fall 2017/Winter 2018 Volume 7, No. 3: Top Doctors in the Puget Sound Area - Urology.

AUA Presidential Citation 2012:
Recognized for outstanding achievements in Men's Health Awareness

CERTIFICATION

Basic Life Support, current certificate.
Advanced Cardiac Life Support, current certificate.

ARTICLES

Advocacy in Male Health: A State Society Story. Urologic Clinics of North America, 39 (2012) 25-31

Solifenacin at 3 Years: A Review of Efficacy and Safety, *Postgraduate Medicine*, Volume 120, Number 2, July 2008: Richard S. Pelman, MD; James P Capo, Jr., MD; and Serio Forero-Schwanhaeuser, MD

Participated in the development of the Comprehensive Cancer Control Plan for the State of Washington, Prostate Cancer Chapter

Authored Overview of Overactive Bladder, Prostatitis and Lower Urinary Tract Symptoms for the Primary Care Physician in *Reviews in Urology*, Volume 6, Supplement 1, 2004, Page 516-523.

Conceived and Edited Manual, *The Urology for Primary Care*. Authored articles on Overactive Bladder, Lower Urinary Tract Symptoms, Bladder Outlet Obstruction and Prostatitis for this manual

Conceived and Organized Washington State Urology Society's *The Guide to Men's Health*, which may be viewed at www.wsus.org/healthguide.
Fibroepithelial Polyp of the Ureter in a Child; AJR: 157, December 1991: Liddell, R.M.; Weinberger, E; Scholfield, D.E.; Pelman, R.S.

OVERACTIVE BLADDER LECTURES AND PRESENTATIONS

Faculty for Primary Care Practitioner CME workshop series: *"Urologic care: (What your patients aren't telling you—Solving these problems and improving your practice." Sponsored by the Physicians Health Care Initiative, 2005.*

Faculty: *The urge for OAB relief: Are your patients dry enough?* teleconference. Physician dialogue sponsored by Astellas Pharma US, Inc. and Glaxo Smith Kline, 2005-2006

Faculty: *Countdown to continence, the pursuit of dryness and improved quality of life in OAB.* CME teleconference sponsored by the Dannemiller Memorial Educational Foundation, and the Customer Link, 2006.

Faculty Pri-Med Institute: *Elevating raising the bar in the management in OAB-patient expectations for quality of life.* 2006

Attendee Overactive Bladder Global Advisory Board. Sponsored by Glaxo Smith Kline. November, 2006, London, England.

Faculty Pri-Med Institute: *The drive for dryness in overactive bladder, steering your patient in the right direction.* 2007

Faculty: A date with dryness: *Meeting today's difficult challenges in overactive bladder.* Responsible for development of course content and faculty. 2007

Faculty: *The urge to define urgency.* Expert opinions on urgency. Study Design and outcomes in OAB. CME sponsored by the Dannemiller Memorial Education Foundation and the Customer Link, American Urological Association, Anaheim, CA, May, 2007

Epocrates OAB CME program *"OAB spotlight: Focus on improving Outcomes"*. In press, 2008.

MALE HEALTH:

Developed The Men's Health Program for the Washington State Urology Society 1993

Developed Men's Health Lecture Series Washington State Urology Society: 1994, 1995, and 1996.

Developed 'The Guide to Men's Health', Washington State Urology Society 2002
Written and Video Guide. View at www.wsus.org - Guide to Men's Health.

Chair: Committee on Men's Health, Washington State Urology Society 1996- present.

Proposed to the American Urological Association's Board of Directors the concept of an AUA Committee on Male Health, April 2009 Chicago Annual meeting.

Developed and served as Chairmen, The American Urological Association's Ad Hoc Committee on Male Health: 2009-2010.

Organized the committee membership and developed goals and agenda for The AUA Committee on Male Health.

Authored with the committee 'Male Health – Urology's Collaborative Future 'First draft of the White Paper on Male Health for the AUA. 2010

Developed with the committee 'The Male Health Checklist' first edit for the AUA 2010

Served as Course Director and Faculty for the inaugural AUA Instructional Course on Male Health – Washington D.C. Annual Meeting, May 15, 2011.

Course Director and Faculty, AUA Instructional Course on Male Health ` 001-IC - Atlanta Georgia. AUA Annual meeting May 19, 2012.

Course Director and Faculty, AUA Post Graduate Course on Male Health, 007PG Male Health: Strategies for Managing Lifelong Wellness – San Diego California, Annual Meeting May 4, 2013.

Course Director and Faculty, AUA Post Graduate Course on Male Health: Strategies for Managing Lifelong Wellness, May 17, 2014 Orlando, Florida AUA Annual meeting

Course Director and Faculty, AUA Post Graduate Course on Male Health 025 PG: Strategies for Managing Lifelong Wellness, May 16, 2015, New Orleans, LA, AUA Annual Meeting

Course Director and Faculty, AUA Post Graduate Course on Male Health PG 055: Strategies for Managing Lifelong Wellness, May 8, 2016 San Diego, California, AUA Annual Meeting

Faculty Extension Course on Male Health, Whistler BC August 26, 2011, Western Section American Urological Association 87th Annual Meeting

Health Initiatives for Men Study:

A Collaborative effort, Departments of Anthropology, Center for Studies in Demography and Ecology, Urology University of Washington, BioBehavioral Health Pennsylvania State University, Premera Blue Cross of Washington
Pilot Project: Study group member
KA O'Connor, PhD. Department of Anthropology, University of Washington, Center for Demography and Ecology, University of Washington
SA Snipes PhD. BioBehavioral Health, Pennsylvania State University,
M Chan Ridley Vivacity, Mountlake Terrace WA
SM Goodreau PhD. Department of Anthropology, University of Washington, Center for Studies in Demography and Ecology, University of Washington.
BC Trumble, PhC, Department of Anthropology, University of Washington, Center for Studies in Demography and Ecology, University of Washington.
DM Morrison, PhD, Center for Studies in Demography and Ecology, University of Washington
BK Shell-Duncan PhD. Chair, Department of Anthropology, University of Washington, Center for Studies in Demography and Ecology, University of Washington.
AC Guyton, PhC, Center for Studies in Demography and Ecology, University of Washington.
TK Hayes Constant, Department of Anthropology, University of Washington, Center for Studies in Demography and Ecology, University of Washington.
RS Pelman, M.D. Department of Urology, University of Washington.

Poster Session IV:

86Th Annual Western Section, American Urological Association Meeting: Poster 196 “Man Up”: Qualitative findings from the Health Initiatives for Men Study. KA O’Connor Presenter.

CLINICAL GUIDELINE | Annals of Internal Medicine

Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement

Virginia A. Moyer, MD, PhD, on behalf of the U.S. Preventive Services Task Force*

Description: Update of the 2008 U.S. Preventive Services Task Force (USPSTF) recommendation statement on screening for prostate cancer.

Methods: The USPSTF reviewed new evidence on the benefits and harms of prostate-specific antigen (PSA)–based screening for prostate cancer, as well as the benefits and harms of treatment of localized prostate cancer.

Recommendation: The USPSTF recommends against PSA-based screening for prostate cancer (grade D recommendation).

This recommendation applies to men in the general U.S. population, regardless of age. This recommendation does not include the use of the PSA test for surveillance after diagnosis or treatment of prostate cancer; the use of the PSA test for this indication is outside the scope of the USPSTF.

Ann Intern Med. 2012;157:120-134. www.annals.org

For author affiliation, see end of text.

* For a list of the members of the USPSTF, see **Appendix 1** (available at www.annals.org).

This article was published at www.annals.org on 22 May 2012.

The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive services for patients without related signs or symptoms.

It bases its recommendations on the evidence of both the benefits and harms of the service, and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

SUMMARY OF RECOMMENDATION AND EVIDENCE

The USPSTF recommends against prostate-specific antigen (PSA)–based screening for prostate cancer (grade D recommendation).

See the Clinical Considerations section for a discussion about implementation of this recommendation.

See also:

Print

Related articles 135, 137

Summary for Patients I-44

Web-Only

CME quiz (preview on page I-23)

See **Figure 1** for a summary of the recommendation and suggestions for clinical practice. **Table 1** describes the USPSTF grades, and **Table 2** describes the USPSTF classification of levels of certainty about net benefit.

RATIONALE

Importance

Prostate cancer is the most commonly diagnosed non–skin cancer in men in the United States, with a lifetime risk for diagnosis currently estimated at 15.9%. Most cases of prostate cancer have a good prognosis even without treatment, but some cases are aggressive; the lifetime risk for dying of prostate cancer is 2.8%. Prostate cancer is rare before age 50 years, and very few men die of prostate cancer before age 60 years. Seventy percent of deaths due to prostate cancer occur after age 75 years (1).

Detection

Contemporary recommendations for prostate cancer screening all incorporate the measurement of serum PSA levels; other methods of detection, such as digital rectal examination or ultrasonography, may be included. There is convincing evidence that PSA-based screening programs result in the detection of many cases of asymptomatic prostate cancer. There is also convincing evidence that a substantial percentage of men who have asymptomatic cancer detected by PSA screening have a tumor that either will not progress or will progress so slowly that it would have remained asymptomatic for the man's lifetime. The terms "overdiagnosis" or "pseudo-disease" are used to describe both situations. The rate of overdiagnosis of prostate cancer increases as the number of men subjected to bi-

Figure 1. **Screening for prostate cancer: clinical summary of U.S. Preventive Services Task Force recommendation.**

Annals of Internal Medicine

U.S. Preventive Services TASK FORCE
www.USPreventiveServicesTaskForce.org

SCREENING FOR PROSTATE CANCER

CLINICAL SUMMARY OF U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

Population	**Adult Males**
Recommendation	**Do not use prostate-specific antigen (PSA)–based screening for prostate cancer.**
	Grade: D

Screening Tests	Contemporary recommendations for prostate cancer screening all incorporate the measurement of serum PSA levels; other methods of detection, such as digital rectal examination or ultrasonography, may be included. There is convincing evidence that PSA-based screening programs result in the detection of many cases of asymptomatic prostate cancer, and that a substantial percentage of men who have asymptomatic cancer detected by PSA screening have a tumor that either will not progress or will progress so slowly that it would have remained asymptomatic for the man's lifetime (i.e., PSA-based screening results in considerable overdiagnosis).
Interventions	Management strategies for localized prostate cancer include watchful waiting, active surveillance, surgery, and radiation therapy. There is no consensus regarding optimal treatment.
Balance of Harms and Benefits	The reduction in prostate cancer mortality 10 to 14 years after PSA-based screening is, at most, very small, even for men in the optimal age range of 55 to 69 years. The harms of screening include pain, fever, bleeding, infection, and transient urinary difficulties associated with prostate biopsy, psychological harm of false-positive test results, and overdiagnosis. Harms of treatment include erectile dysfunction, urinary incontinence, bowel dysfunction, and a small risk for premature death. Because of the current inability to reliably distinguish tumors that will remain indolent from those destined to be lethal, many men are being subjected to the harms of treatment for prostate cancer that will never become symptomatic. The benefits of PSA-based screening for prostate cancer do not outweigh the harms.
Other Relevant USPSTF Recommendations	Recommendations on screening for other types of cancer can be found at www.uspreventiveservicestaskforce.org.

For a summary of the evidence systematically reviewed in making this recommendation, the full recommendation statement, and supporting documents, please go to www.uspreventiveservicestaskforce.org.

opsy increases. The number of cancer cases that could be detected in a screened population is large; a single study in which men eligible for PSA screening had biopsy regardless of PSA level detected cancer in nearly 25% of men (2). The rate of overdiagnosis also depends on life expectancy at the time of diagnosis. A cancer diagnosis in men with shorter life expectancies because of chronic diseases or age is much more likely to be overdiagnosis. The precise magnitude of overdiagnosis associated with any screening and treatment program is difficult to determine, but estimates from the 2 largest trials suggest overdiagnosis rates of 17% to 50% for prostate cancer screening (3).

Benefits of Detection and Early Treatment

The primary goal of prostate cancer screening is to reduce deaths due to prostate cancer and, thus, increase length of life. An additional important outcome would be a reduction in the development of symptomatic metastatic disease. Reduction in prostate cancer mortality was the primary outcome used in available randomized, controlled trials of prostate cancer screening. Although 1 screening trial reported on the presence of metastatic disease at the time of prostate cancer diagnosis, no study reported on the effect of screening on the development of subsequent metastatic disease, making it difficult to assess the effect of lead-time bias on the reported rates.

Men with screen-detected cancer can potentially fall into 1 of 3 categories: those whose cancer will result in death despite early diagnosis and treatment, those who will have good outcomes in the absence of screening, and those for whom early diagnosis and treatment improve survival. Only randomized trials of screening allow an accurate estimate of the number of men who fall into the last category. There is convincing evidence that the number of men who avoid dying of prostate cancer because of screening after 10 to 14 years is, at best, very small. Two major trials of PSA screening were considered by the USPSTF: the U.S. PLCO (Prostate, Lung, Colorectal, and Ovarian) Cancer Screening Trial and the ERSPC (European Randomized Study of Screening for Prostate Cancer). The

Table 1. **What the USPSTF Grades Mean and Suggestions for Practice**

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	*Note: The following statement is undergoing revision.* Clinicians may provide this service to selected patients depending on individual circumstances. However, for most persons without signs or symptoms there is likely to be only a small benefit from this service.	Offer/provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

U.S. trial did not demonstrate any reduction of prostate cancer mortality. The European trial found a reduction in prostate cancer deaths of approximately 1 death per 1000 men screened in a subgroup aged 55 to 69 years. This result was heavily influenced by the results of 2 countries; 5 of the 7 countries reporting results did not find a statistically significant reduction. All-cause mortality in the European trial was nearly identical in the screened and nonscreened groups.

There is adequate evidence that the benefit of PSA screening and early treatment ranges from 0 to 1 prostate cancer deaths avoided per 1000 men screened.

Table 2. **USPSTF Levels of Certainty Regarding Net Benefit**

Level of Certainty*	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: the number, size, or quality of individual studies; inconsistency of findings across individual studies; limited generalizability of findings to routine primary care practice; and lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: the limited number or size of studies; important flaws in study design or methods; inconsistency of findings across individual studies; gaps in the chain of evidence; findings that are not generalizable to routine primary care practice; and a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

* The USPSTF defines *certainty* as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general primary care population. The USPSTF assigns a certainty level on the basis of the nature of the overall evidence available to assess the net benefit of a preventive service.

Harms of Detection and Early Treatment

Harms Related to Screening and Diagnostic Procedures

Convincing evidence demonstrates that the PSA test often produces false-positive results (approximately 80% of positive PSA test results are false-positive when cutoffs between 2.5 and 4.0 μg/L are used) (4). There is adequate evidence that false-positive PSA test results are associated with negative psychological effects, including persistent worry about prostate cancer. Men who have a false-positive test result are more likely to have additional testing, including 1 or more biopsies, in the following year than those who have a negative test result (5). Over 10 years, approximately 15% to 20% of men will have a PSA test result that triggers a biopsy, depending on the PSA threshold and testing interval used (4). New evidence from a randomized trial of treatment of screen-detected cancer indicates that roughly one third of men who have prostate biopsy experience pain, fever, bleeding, infection, transient urinary difficulties, or other issues requiring clinician follow-up that the men consider a "moderate or major problem"; approximately 1% require hospitalization (6).

The USPSTF considered the magnitude of these harms associated with screening and diagnostic procedures to be at least small.

Harms Related to Treatment of Screen-Detected Cancer

Adequate evidence shows that nearly 90% of men with PSA-detected prostate cancer in the United States have early treatment with surgery, radiation, or androgen deprivation therapy (7, 8). Adequate evidence shows that up to 5 in 1000 men will die within 1 month of prostate cancer

surgery and between 10 and 70 men will have serious complications but survive. Radiotherapy and surgery result in long-term adverse effects, including urinary incontinence and erectile dysfunction in at least 200 to 300 of 1000 men treated with these therapies. Radiotherapy is also associated with bowel dysfunction (9, 10).

Some clinicians have used androgen deprivation therapy as primary therapy for early-stage prostate cancer, particularly in older men, although this is not a U.S. Food and Drug Administration (FDA)–approved indication and it has not been shown to improve survival in localized prostate cancer. Adequate evidence shows that androgen deprivation therapy for localized prostate cancer is associated with erectile dysfunction (in approximately 400 of 1000 men treated), as well as gynecomastia and hot flashes (9, 10).

There is convincing evidence that PSA-based screening leads to substantial overdiagnosis of prostate tumors. The amount of overdiagnosis of prostate cancer is an important concern because a man with cancer that would remain asymptomatic for the remainder of his life cannot benefit from screening or treatment. There is a high propensity for physicians and patients to elect to treat most cases of screen-detected cancer, given our current inability to distinguish tumors that will remain indolent from those destined to be lethal (7, 11). Thus, many men are being subjected to the harms of treatment of prostate cancer that will never become symptomatic. Even for men whose screen-detected cancer would otherwise have been later identified without screening, most experience the same outcome and are, therefore, subjected to the harms of treatment for a much longer period (12, 13). There is convincing evidence that PSA-based screening for prostate cancer results in considerable overtreatment and its associated harms.

The USPSTF considered the magnitude of these treatment-associated harms to be at least moderate.

USPSTF Assessment

Although the precise, long-term effect of PSA screening on prostate cancer–specific mortality remains uncertain, existing studies adequately demonstrate that the reduction in prostate cancer mortality after 10 to 14 years is, at most, very small, even for men in what seems to be the optimal age range of 55 to 69 years. There is no apparent reduction in all-cause mortality. In contrast, the harms associated with the diagnosis and treatment of screen-detected cancer are common, occur early, often persist, and include a small but real risk for premature death. Many more men in a screened population will experience the harms of screening and treatment of screen-detected disease than will experience the benefit. The inevitability of overdiagnosis and overtreatment of prostate cancer as a result of screening means that many men will experience the adverse effects of diagnosis and treatment of a disease that would have remained asymptomatic throughout their lives. Assessing the balance of benefits and harms requires weighing a moderate to high probability of early and persistent harm from treatment against the very low probability of preventing a death from prostate cancer in the long term.

The USPSTF concludes that there is moderate certainty that the benefits of PSA-based screening for prostate cancer do not outweigh the harms.

Clinical Considerations

Implementation

Although the USPSTF discourages the use of screening tests for which the benefits do not outweigh the harms in the target population, it recognizes the common use of PSA screening in practice today and understands that some men will continue to request screening and some physicians will continue to offer it. The decision to initiate or continue PSA screening should reflect an explicit understanding of the possible benefits and harms and respect the patients' preferences. Physicians should not offer or order PSA screening unless they are prepared to engage in shared decision making that enables an informed choice by the patients. Similarly, patients requesting PSA screening should be provided with the opportunity to make informed choices to be screened that reflect their values about specific benefits and harms. Community- and employer-based screening should be discontinued. **Table 3** presents reasonable estimates of the likely outcomes of screening, given the current approach to screening and treatment of screen-detected prostate cancer in the United States.

The treatment of some cases of clinically localized prostate cancer can change the natural history of the disease and may reduce morbidity and mortality in a small percentage of men, although the prognosis for clinically localized cancer is generally good regardless of the method of detection, even in the absence of treatment. The primary goal of PSA-based screening is to find men for whom treatment would reduce morbidity and mortality. Studies demonstrate that the number of men who experience this benefit is, at most, very small, and PSA-based screening as currently implemented in the United States produces more harms than benefits in the screened population. It is not known whether an alternative approach to screening and management of screen-detected disease could achieve the same or greater benefits while reducing the harms. Focusing screening on men at increased risk for prostate cancer mortality may improve the balance of benefits and harms, but existing studies do not allow conclusions about a greater absolute or relative benefit from screening in these populations. Lengthening the interval between screening tests may reduce harms without affecting cancer mortality; the only screening trial that demonstrated a prostate cancer–specific mortality benefit generally used a 2- to 4-year screening interval (15). Other potential ways to reduce diagnostic- and treatment-related harms include in-

Table 3. **PSA-Based Screening for Prostate Cancer***

Why not screen for prostate cancer?	
Screening may benefit a small number of men but will result in harm to many others. A person choosing to be screened should believe that the possibility of benefit is more important than the risk for harm. The USPSTF assessment of the balance of benefits and harms in a screened population is that the benefits do not outweigh the harms.	
What are the benefits and harms of screening 1000 men aged 55–69 y† with a PSA test every 1–4 y for 10 y?	
Possible benefit of screening	**Men, *n***
Reduced 10 y risk for dying of prostate cancer	
Die of prostate cancer with no screening	5 in 1000
Die of prostate cancer with screening	4–5 in 1000
Do not die of prostate cancer because of screening	0–1 in 1000
Harms of screening	
At least 1 false-positive screening PSA test result	
Most positive test results lead to biopsy. Of men having biopsy, up to 33% will have moderate or major bothersome symptoms, including pain, fever, bleeding, infection, and temporary urinary difficulties; 1% will be hospitalized.	100–120 in 1000
Prostate cancer diagnosis	
Although a diagnosis of prostate cancer may not be considered a harm, currently 90% of diagnosed men are treated and, thus, are at risk for the harms of treatment. A large majority of the men who are being treated would do well without treatment. A substantial percentage of these men would have remained asymptomatic for life.	110 in 1000
Complications of treatment (among persons who are screened)‡	
Develop serious cardiovascular events due to treatment	2 in 1000
Develop deep venous thrombosis or pulmonary embolus due to treatment	1 in 1000
Develop erectile dysfunction due to treatment	29 in 1000
Develop urinary incontinence due to treatment	18 in 1000
Die due to treatment	<1 in 1000

PSA = prostate-specific antigen.
* The table design is adapted from Woloshin and Schwartz (14). Calculations of the estimated benefits and harms rely on assumptions and are, by nature, somewhat imprecise. Estimates should be considered in the full context of clinical decision making and used to stimulate shared decision making.
† The best evidence of possible benefit of PSA screening is in men aged 55–69 y.
‡ The rate of complications depends on the proportion of men having treatment and the method of treatment. The table reflects a distribution of 60% surgical treatment, 30% radiation, and 10% observation (see **Appendix 2**, available at www.annals.org, for more details about assumptions and references). Other harms of radiation, such as bowel damage, are not shown.

creasing the PSA threshold used to trigger the decision for biopsy or need for treatment (12, 16), or reducing the number of men having active treatment at the time of diagnosis through watchful waiting or active surveillance (11). Periodic digital rectal examinations could also be an alternative strategy worthy of further study. In the only randomized trial demonstrating a mortality reduction from radical prostatectomy for clinically localized cancer, a high percentage of men had palpable cancer (17). All of these approaches require additional research to better elucidate their merits and pitfalls and more clearly define an approach to the diagnosis and management of prostate cancer that optimizes the benefits while minimizing the harms.

Patient Population Under Consideration

This recommendation applies to men in the general U.S. population. Older age is the strongest risk factor for the development of prostate cancer. However, neither screening nor treatment trials show benefit in men older than 70 years. Across age ranges, black men and men with a family history of prostate cancer have an increased risk of developing and dying of prostate cancer. Black men are approximately twice as likely to die of prostate cancer than other men in the United States (1), and the reason for this disparity is unknown. Black men represented a small minority of participants in the randomized clinical trials of screening (4% of enrolled men in the PLCO trial were non-Hispanic black; although the ERSPC and other trials did not report the specific racial demographic characteristics of participants, they probably were predominately white). Thus, no firm conclusions can be made about the balance of benefits and harms of PSA-based screening in this population. However, it is problematic to selectively recommend PSA-based screening for black men in the absence of data that support a more favorable balance of risks and benefits. A higher incidence of cancer will result in more diagnoses and treatments, but the increase may not be accompanied by a larger absolute reduction in mortality. Preliminary results from PIVOT (Prostate Cancer Intervention Versus Observation Trial), in which 30% of enrollees were black, have become available since the publication of the USPSTF's commissioned evidence reviews. Investigators found no difference in outcomes due to treatment of prostate cancer in black men compared with white men (12).

Exposure to Agent Orange (a defoliant used in the Vietnam War) is considered to be a risk factor for prostate cancer, although few data exist on the outcomes or effect of PSA testing and treatment in these persons. Prostate cancer in Vietnam veterans who were exposed to Agent Orange is considered a service-connected condition by the Veterans Health Administration.

The USPSTF did not evaluate the use of the PSA test as part of a diagnostic strategy in men with symptoms potentially suggestive of prostate cancer. However, the presence of urinary symptoms was not an inclusion or exclusion criterion in screening or treatment trials, and approximately one quarter of men in screening trials had bothersome lower urinary tract symptoms (nocturia, urgency, frequency, and poor stream). The presence of benign prostatic hyperplasia is not an established risk factor for prostate cancer, and the risk for prostate cancer among men with elevated PSA levels is lower in men with urinary symptoms than in men without symptoms (18).

This recommendation also does not include the use of the PSA test for surveillance after diagnosis or treatment of prostate cancer and does not consider PSA-based testing in men with known BRCA gene mutations who may be at increased risk for prostate cancer.

Screening Tests

Prostate-specific antigen–based screening in men aged 50 to 74 years has been evaluated in 5 unique randomized, controlled trials of single or interval PSA testing with various PSA cutoffs and screening intervals, along with other screening methods, such as digital rectal examination or transrectal ultrasonography (4, 19–22). Screening tests or programs that do not incorporate PSA testing, including digital rectal examination alone, have not been adequately evaluated in controlled studies.

The PLCO trial found a nonstatistically significant increase in prostate cancer mortality in the annual screening group at 11.5 and 13 years, with results consistently favoring the usual care group (19, 23).

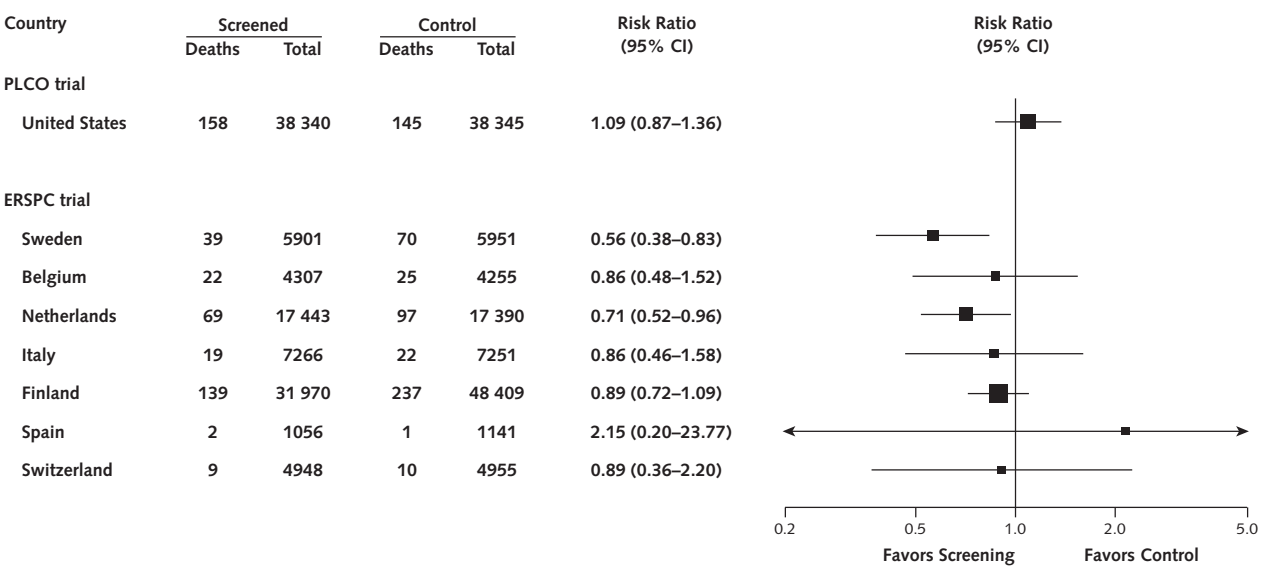
A prespecified subgroup analysis of men aged 55 to 69 years in the ERSPC trial demonstrated a prostate cancer mortality rate ratio (RR) of 0.80 (95% CI, 0.65 to 0.98) in screened men after a median follow-up of 9 years, with similar findings at 11 years (RR, 0.79 [CI, 0.68 to 0.91]) (4, 15). Of the 7 centers included in the ERSPC analysis, only 2 countries (Sweden and the Netherlands) reported statistically significant reductions in prostate cancer mortality after 11 years (5 did not), and these results seem to drive the overall benefit found in this trial (**Figure 2**) (15). No study reported any factors, including patient age, adherence to site or study protocol, length of follow-up, PSA thresholds, or intervals between tests, that could clearly explain why mortality reductions were larger in Sweden or the Netherlands than in other European countries or the United States (PLCO trial). Combining the results through meta-analysis may be inappropriate due to clinical and methodological differences across trials.

No study found a difference in overall or all-cause mortality. This probably reflects the high rates of competing mortality in this age group, because these men are more likely to die of prostate cancer, as well as the limited power of prostate cancer screening trials to detect differences in all-cause mortality, should they exist. Even in the "core" age group of 55 to 69 years in the ERSPC trial, only 462 of 17 256 deaths were due to prostate cancer. The all-cause mortality RR was 1.00 (CI, 0.98 to 1.02) in all men randomly assigned to screening versus no screening. Results were similar in men aged 55 to 69 years (15). The absence of any trend toward a reduction in all-cause mortality is particularly important in the context of the difficulty of attributing death to a specific cause in this age group.

Treatment

Primary management strategies for PSA-detected prostate cancer include watchful waiting (observation and physical examination with palliative treatment of symptoms), active surveillance (periodic monitoring with PSA tests, physical examinations, and repeated prostate biopsy) with conversion to potentially curative treatment at the sign of disease progression or worsening prognosis, and surgery or radiation therapy (24). There is no consensus about the optimal treatment of localized disease. From

Figure 2. **Relative risk of prostate cancer death for men screened with PSA versus control participants, by country.**



ERSPC = European Randomized Study of Screening for Prostate Cancer; PLCO = Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial; PSA = prostate-specific antigen.

1986 through 2005, PSA-based screening probably resulted in approximately 1 million additional U.S. men being treated with surgery, radiation therapy, or both compared with the time before the test was introduced (7).

At the time of the USPSTF's commissioned evidence review, only 1 recent randomized, controlled trial of surgical treatment versus observation for clinically localized prostate cancer was available (13). In the Scandinavian Prostate Cancer Group Study 4 trial, surgical management of localized, primarily clinically detected prostate cancer was associated with an approximate 6% absolute reduction in prostate cancer and all-cause mortality at 12 to 15 years of follow-up; benefit seemed to be limited to men younger than 65 years (13). Subsequently, preliminary results were reported from another randomized trial that compared external beam radiotherapy (EBRT) with watchful waiting in 214 men with localized prostate cancer detected before initiation of PSA screening. At 20 years, survival did not differ between men randomly assigned to watchful waiting or EBRT (31% vs. 35%; $P = 0.26$). Prostate cancer mortality at 15 years was high in each group but did not differ between groups (23% vs. 19%; $P = 0.51$). External beam radiotherapy did reduce distant progression and recurrence-free survival (25). In men with localized prostate cancer detected in the early PSA screening era, preliminary findings from PIVOT show that, after 12 years, intention to treat with radical prostatectomy did not reduce disease-specific or all-cause mortality compared with observation; absolute differences were less than 3% and not statistically different (12). An ongoing trial in the United Kingdom (ProtecT [Prostate Testing for Cancer and Treatment]) comparing radical prostatectomy with EBRT or active surveillance has enrolled nearly 2000 men with PSA-detected prostate cancer. Results are expected in 2015 (26).

Up to 0.5% of men will die within 30 days of having radical prostatectomy, and 3% to 7% will have serious surgical complications. Compared with men who choose watchful waiting, an additional 20% to 30% or more of men treated with radical prostatectomy will experience erectile dysfunction, urinary incontinence, or both after 1 to 10 years. Radiation therapy is also associated with increases in erectile, bowel, and bladder dysfunction (9, 10).

OTHER CONSIDERATIONS

Research Needs and Gaps

Because the balance of benefits and harms of prostate cancer screening is heavily influenced by overdiagnosis and overtreatment, research is needed to identify ways to reduce the occurrence of these events, including evaluating the effect of altering PSA thresholds for an abnormal test or biopsy result on false-positive rates and the detection of indolent disease.

Similarly, research is urgently needed to identify new screening methods that can distinguish nonprogressive or slowly progressive disease from disease that is likely to affect quality or length of life, because this would reduce the number of men who require biopsy and subsequent treatment of disease that has a favorable prognosis without intervention. Additional research is also needed to evaluate the benefits and harms of modifying the use of existing prostate cancer screening tools. Research is needed to assess the effect of using higher PSA thresholds to trigger a diagnostic prostate biopsy, extending intervals between testing, and the role of periodic digital rectal examinations by trained clinicians. Although not well-studied, these strategies may reduce overdiagnosis and overtreatment, and evidence suggests that they may be associated with decreased mortality. Research is also needed to compare the long-term benefits and harms of immediate treatment versus observation with delayed intervention or active surveillance in men with screen-detected prostate cancer. Two randomized, controlled trials, PIVOT (27) and the ProtecT trial (28), are studying this issue. Preliminary results from PIVOT potentially support increasing the PSA threshold for recommending a biopsy or curative treatments in men subsequently diagnosed with prostate cancer.

Additional research is needed to determine whether the balance of benefits and harms of prostate cancer screening differs in men at higher risk of developing or dying of prostate cancer, including black men and those with a family history of the disease.

Accurately ascertaining cause of death in older persons can be problematic; as such, basing clinical recommendations on disease-specific mortality in the absence of an effect on all-cause mortality may not completely capture the health effect and goals of a screening and treatment program. Additional research is required to better assess and improve the reliability of prostate cancer mortality as a valid outcome measure in clinical trials, as well as the best application of the concomitant use of all-cause mortality.

Two large randomized, controlled trials of 5α-reductase inhibitors (finasteride and dutasteride) have shown that these drugs reduce the risk for prostate cancer in men receiving regular PSA tests. However, the observed reduction resulted from a decreased incidence of low-grade prostate cancer alone (Gleason score $\leq$6). The FDA has not approved finasteride or dutasteride for prevention of prostate cancer, concluding that the drugs do not possess a favorable risk–benefit profile for this indication. The FDA cited associated adverse effects, including loss of libido and erectile dysfunction, but most important it noted that there was an absolute increase in the incidence of high-grade prostate cancer in men randomly assigned to finasteride or dutasteride compared with control participants in both trials (29). Additional research would be useful to better understand whether these drugs are associated with the development of high-grade prostatic lesions, determine the effect of 5α-reductase inhibitors (or other potential preventive agents) on prostate cancer mortality, and identify the population that may benefit most from prostate

cancer prevention (with these or other chemoprevention strategies).

Research is needed to better understand patient and provider knowledge and values about the known risks and benefits of prostate cancer screening and treatment, as well as to develop and implement effective informed decision-making materials that accurately convey the best evidence and can be instituted in primary care settings across varied patient groups (for example, by race, age, or family history).

Response to Public Comments

A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 11 October to 13 December 2011. Commenters expressed concern that a grade D recommendation from the USPSTF would preclude the opportunity for discussion between men and their personal health care providers, interfere with the clinician–patient relationship, and prevent men from being able to make their own decisions about whether to be screened for prostate cancer. Some commenters asked that the USPSTF change its recommendation to a grade C to allow men to continue to make informed decisions about screening. Recommendations from the USPSTF are chosen on the basis of the risk–benefit ratio of the intervention: A grade D recommendation means that the USPSTF has concluded that there is at least moderate certainty that the harms of doing the intervention equal or outweigh the benefits in the target population, whereas a grade C recommendation means that the USPSTF has concluded that there is at least moderate certainty that the overall net benefit of the service is small. The USPSTF could not assign a grade C recommendation for PSA screening because it did not conclude that the benefits outweigh the harms. In the Implementation section, the USPSTF has clarified that a D recommendation does not preclude discussions between clinicians and patients to promote informed decision making that supports personal values and preferences.

Some commenters requested that the USPSTF provide more information about the consequences of avoiding PSA screening. A summary of the benefits and harms of screening can be found in **Table 3**. In summary, the USPSTF concluded that choosing not to have PSA testing will result in a patient living a similar length of life, with little to no difference in prostate cancer–specific mortality, while avoiding harms associated with PSA testing and subsequent diagnostic procedures and treatments.

Commenters were concerned that the USPSTF did not adequately consider a separate recommendation for black men. Additional information about this population can be found in the Patient Population Under Consideration section.

Many commenters mistakenly believed that the USPSTF either relied solely on the PLCO trial or published meta-analyses or did its own meta-analysis to reach its conclusions about the efficacy of PSA-based screening. Although the commissioned systematic evidence review summarized the findings of 2 previously published meta-analyses because they met the minimum inclusion requirements for the report, neither the authors of that review nor the USPSTF did a new meta-analysis. The USPSTF is aware of the heterogeneity in the available randomized trials of prostate cancer screening and the limitations of meta-analysis in this situation. Both the ERSPC and PLCO trials were heavily weighted by the USPSTF in its considerations, because they had the largest populations and were of the highest quality, although both had important—but different—methodological limitations. The screening intervals, PSA thresholds, use of digital rectal examinations, enrollee characteristics, and follow-up diagnostic and treatment strategies used in the PLCO trial are most applicable to current U.S. settings and practice patterns.

Commenters asked the USPSTF to consider evidence from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) database, showing that prostate cancer mortality decreased by 40% in the United States between 1992 and 2007 (30). Many suggested that the decline must be attributable to the effect of screening, because PSA-based screening was introduced in the United States in the early 1990s and became widespread by the mid-1990s to late 1990s. The challenge of ecologic data is that it is impossible to reliably separate out the relative effects of any changes in screening, diagnosis, or treatment practices (or fundamental changes in the underlying risk of developing or dying of the disease in the population due to a multiplicity of other causes) that may have been occurring simultaneously over a given period. All of these, including screening, may have played some role in the decline seen in mortality; however, only a randomized trial can determine with confidence the magnitude of effect that can be attributable to a given intervention. According to the SEER database, in the 1970s and 1980s, before the introduction of widespread PSA screening, prostate cancer mortality rates started at 29.9 cases per 100 000 men and showed a slow but constant increase over time. The reason for this increase is unknown. Mortality from prostate cancer peaked between 1991 and 1993—roughly the same time when PSA tests became a common clinical practice—at 39.3 cases per 100 000 men, and began to decline by approximately 1 to 2 cases per 100 000 men per year after this point (2007 rate, 24.0 cases per 100 000 men). Information from randomized trials suggests that any potential mortality benefit from screening will not occur for 7 to 10 years. As such, it would be very unlikely that any decline in mortality rates from 1990 to 2000 would be related to screening.

Some commenters believed that the USPSTF should have considered a reduction in morbidity due to prostate cancer as an outcome, not just mortality. The rate of met-

astatic disease should roughly parallel the rate of deaths; if a large difference in metastatic disease was present between the intervention and control groups of the ERSPC and PLCO trials at 11 and 13 years of follow-up, a larger effect on the reduction in mortality would have been expected. Although the USPSTF agrees that a demonstrated effect of PSA-based screening on long-term quality of life or functional status would be an important outcome to consider, insufficient data are available from screening trials to draw such a conclusion. The ERSPC trial provides information about the incidence of metastatic disease only at the time of diagnosis, rather than longitudinal follow-up for the development of such disease in screened versus unscreened populations. Data on quality of life are available from randomized treatment trials of early-stage prostate cancer and suggest that treatment with observation or watchful waiting provides similar long-term quality of life as early intervention, with marked reduction in treatment-related adverse effects (31, 32).

Many commenters asked the USPSTF to review a publication reporting that the efficacy of PSA-based screening in the PLCO trial was affected by comorbidity status (33); they believed that this provided evidence that PSA-based screening could be recommended for very healthy men. In the article, Crawford and colleagues (33) reported that the hazard ratio for death in men without comorbid conditions in the annual screening versus the usual care group was 0.56 (CI, 0.33 to 0.95). However, the PLCO investigators later reported, as part of their extended follow-up of the trial, that this finding was sensitive to the definition of comorbidity used (23). Crawford and colleagues chose an expanded definition of comorbidity that included both "standard" Charlson comorbidity index conditions and hypertension (even if it was well-controlled), diverticulosis, gallbladder disease, and obesity. When the analysis was repeated by using only validated measures of comorbidity (that is, Charlson comorbidity index conditions only), an interaction was no longer seen. Several researchers (including PLCO investigators) have questioned the biological plausibility of this finding by Crawford and colleagues, noting, among other reasons, that the positive interaction seems to be largely driven by the inclusion of hypertension and obesity, conditions that seem to convey minimal excess treatment risks or differences in treatment options. These researchers also note that although Crawford and colleagues initially argue that comorbid conditions lessen the effectiveness of treatment (thus, causing screening to be ineffective in less healthy men), participants in the usual care group with a greater degree of comorbidity actually had a statistically significant lower risk for dying of prostate cancer than healthier men (23, 34). Preliminary results from PIVOT also found that the effect of radical prostatectomy compared with observation did not vary by comorbidity or health status (12).

DISCUSSION

Burden of Disease

An estimated 240 890 U.S. men received a prostate cancer diagnosis in 2011, and an estimated 33 720 men died of the disease (35). The average age of diagnosis was 67 years and the median age of those who died of prostate cancer from 2003 through 2007 was 80 years; 71% of deaths occurred in men older than 75 years (1). Black men have a substantially higher prostate cancer incidence rate than white men (232 vs. 146 cases per 100 000 men) and more than twice the prostate cancer mortality rate (56 vs. 24 deaths per 100 000 men, respectively) (35).

Prostate cancer is a clinically heterogeneous disease. Autopsy studies have shown that approximately one third of men aged 40 to 60 years have histologically evident prostate cancer (36); the proportion increases to as high as three fourths in men older than 85 years (37). Most cases represent microscopic, well-differentiated lesions that are unlikely to be clinically important. Increased frequency of PSA testing, a lower threshold for biopsy, and an increase in the number of core biopsies obtained all increase the detection of lesions that are unlikely to be clinically significant.

Scope of Review

The previous evidence update, done for the USPSTF in 2008, found insufficient evidence that screening for prostate cancer improved health outcomes, including prostate cancer–specific and all-cause mortality, for men younger than 75 years. In men aged 75 years or older, the USPSTF found adequate evidence that the incremental benefits of treatment of screen-detected prostate cancer are small to none and that the harms of screening and treatment outweigh any potential benefits (38). After the publication of initial mortality results from 2 large randomized, controlled trials of prostate cancer screening, the USPSTF determined that a targeted update of the direct evidence on the benefits of PSA-based screening for prostate cancer should be done (39). In addition, the USPSTF requested a separate systematic review of the benefits and harms of treatment of localized prostate cancer (10). Since the release of the USPSTF's draft recommendation statement on prostate cancer screening and its supporting systematic evidence reviews, updated results from the ERSPC and PLCO trials and data on harms related to prostate biopsy from the ProtecT trial have become available; these publications were used to inform this final recommendation statement.

Accuracy of Screening

The conventional PSA cutoff of 4.0 μg/L detects many cases of prostate cancer; however, some cases will be missed. Using a lower cutoff detects more cases of cancer, but at the cost of labeling more men as potentially having cancer. For example, decreasing the PSA cutoff to 2.5 μg/L would more than double the number of U.S. men aged 40 to 69 years with abnormal results (16), most of which

would be false-positive. It also increases the likelihood of detection of indolent tumors with no clinical importance. Conversely, increasing the PSA cutoff to greater than 10.0 μg/L would reduce the number of men aged 50 to 69 years with abnormal results from approximately 1.2 million to roughly 352 000 (16). There is no PSA cutoff at which a man can be guaranteed to be free from prostate cancer (40).

There are inherent problems with the use of needle biopsy results as a reference standard to assess the accuracy of prostate cancer screening tests. Biopsy detection rates vary according to the number of biopsies done during a single procedure; the more biopsies done, the more cancer cases detected. More cancer cases detected with a "saturation" biopsy procedure (≥20 core biopsies) tend to increase the apparent specificity of an elevated PSA level; however, many of the additional cancer cases detected this way are unlikely to be clinically important. Thus, the accuracy of the PSA test for detecting clinically important prostate cancer cases cannot be determined with precision.

Variations of PSA screening, including the use of age-adjusted PSA cutoffs; free PSA; and PSA density, velocity, slope, and doubling time, have been proposed to improve detection of clinically important cases of prostate cancer. However, no evidence has demonstrated that any of these testing strategies improve health outcomes, and some may even generate harms. One study found that using PSA velocity in the absence of other indications could lead to 1 in 7 men having a biopsy with no increase in predictive accuracy (41).

Effectiveness of Early Detection and Treatment

Two poor-quality (high risk of bias) randomized, controlled trials initiated in the 1980s in Sweden each demonstrated a nonstatistically significant trend toward increased prostate cancer mortality in groups invited to screening (21, 22). A third poor-quality (high risk of bias) trial from Canada showed similar results when an intention-to-screen analysis was used (20). The screening protocols for these trials varied; all included 1 or more PSA tests with cutoffs ranging from 3.0 to 10.0 μg/L; in addition, digital rectal examination and transrectal ultrasonography were variably used.

The more recently published PLCO and ERSPC trials were the principal trials considered by the USPSTF. The fair-quality prostate component of the PLCO trial randomly assigned 76 685 men aged 55 to 74 years to annual PSA screening for 6 years (and concomitant digital rectal examination for 4 years) or to usual care. It used a PSA cutoff of 4.0 μg/L. Diagnostic follow-up for positive screening test results and treatment choices were made by the participant and his personal physician; 90% of men with prostate cancer diagnoses received active treatment (surgery, radiation, hormonal therapy, or some combination). After 7 years (complete follow-up), a nonstatistically significant trend toward increased prostate cancer mortality was seen in the screened group (RR, 1.14 [CI, 0.75 to 1.70]) compared with men in the control group (19). Similar findings were seen after 13 years (RR, 1.09 [CI, 0.87 to 1.36]) (23). The primary criticism of this study relates to the high contamination rate; approximately 50% of men in the control group received at least 1 PSA test during the study, although the investigators increased both the number of screening intervals and the duration of follow-up to attempt to compensate for the contamination effects. In addition, approximately 40% of participants had received a PSA test in the 3 years before enrollment, although subgroup analyses stratified by history of PSA testing before study entry did not reveal differential effects on prostate cancer mortality rates (19). Contamination may attenuate differences in the 2 groups but would not explain both an increased prostate cancer incidence and mortality rate in men assigned to screening.

The fair-quality ERSPC trial randomly assigned 182 160 men aged 50 to 74 years from 7 European countries to PSA testing every 2 to 7 years or to usual care. Prostate-specific antigen cutoffs ranged from 2.5 to 4.0 μg/L, depending on study center (1 center used a cutoff of 10.0 μg/L for several years). Subsequent diagnostic procedures and treatment also varied by center. Sixty-six percent of men who received a prostate cancer diagnosis chose immediate treatment (surgery, radiation therapy, hormonal therapy, or some combination). Among all men who were randomly assigned, there was a borderline reduction in prostate cancer mortality in the screened group after a median follow-up of 9 years (RR, 0.85 [CI, 0.73 to 1.00]) (4). Similar results were reported after 11 years of follow-up and were statistically significant (RR, 0.83 [CI, 0.72 to 0.94]) (15). After a median follow-up of 9 years in a prespecified subgroup analysis limited to men aged 55 to 69 years, a statistically significant reduction in prostate cancer deaths was seen in the screened group (RR, 0.80 [CI, 0.65 to 0.98]) (4). After 11 years of follow-up, a similar reduction was seen (RR, 0.79 [CI, 0.45 to 0.85]); the authors estimated that 1055 men needed to be invited to screening and 37 cases of prostate cancer needed to be detected to avoid 1 death from prostate cancer (15). Of the 7 individual centers included in the mortality analysis, 2 (Sweden and the Netherlands) demonstrated statistically significant reductions in prostate cancer deaths with PSA screening. The magnitude of effect was considerably greater in these 2 centers than in other countries (**Figure 2**). Primary criticisms of this study relate to inconsistencies in age requirements, screening intervals, PSA thresholds, and enrollment procedures used among the study centers, as well as the exclusion of data from 2 study centers in the analysis. There is also concern that differential treatments between the study and control groups may have had an effect on outcomes. Of note, men in the screened group were more likely than men in the control group to have been treated in a university setting, and control participants with high-risk prostate cancer were more likely than screened partic-

ipants to receive radiotherapy, expectant management, or hormonal therapy instead of radical prostatectomy (42). Furthermore, ascertainment of cause of death in men with a diagnosis of prostate cancer included men whose prostate cancer was detected at autopsy. How this cause-of-death adjudication process may affect estimates is unknown, but previous research has demonstrated difficulties in accurately ascertaining cause of death and that small errors could have an important effect on results (43, 44).

After publication of the initial ERSPC mortality results, a single center from within that trial (in Göteborg, Sweden) reported data separately. Outcomes for 60% of this center's participants were reported as part of the full ERSPC publication, and the subsequent country-specific results within the ERSPC trial reflect the separately reported results from Sweden (which included some men not included in the overall ERSPC trial) (45).

Few randomized, controlled trials have compared treatments for localized prostate cancer with watchful waiting. A randomized, controlled trial of 695 men with localized prostate cancer (Scandinavian Prostate Cancer Group Study 4) reported an absolute reduction in the risk for distant metastases (11.7% [CI, 4.8% to 18.6%]) in patients assigned to radical prostatectomy versus watchful waiting after 15 years of follow-up. An absolute reduction in prostate cancer mortality (6.1% [CI, 0.2% to 12.0%]) and a trend toward a reduction in all-cause mortality (6.6% [CI, −1.3% to 14.5%]) were also seen over this period. Subgroup analysis suggests that the benefits of prostatectomy were limited to men aged 65 years or younger. The applicability of these findings to cancer detected by PSA-based screening is limited, because only 5% of participants were diagnosed with prostate cancer through some form of screening, 88% had palpable tumors, and more than 40% presented with symptoms (13, 17). An earlier, poor-quality study found no mortality reduction from radical prostatectomy versus watchful waiting after 23 years of follow-up (46). Another randomized trial of 214 men with localized prostate cancer detected before initiation of PSA screening that compared EBRT versus watchful waiting presented preliminary mortality results after completion of the evidence review. At 20 years, the observed survival did not differ between men randomly assigned to watchful waiting and EBRT (31% vs. 35%; $P = 0.26$). Prostate cancer mortality at 15 years was high in each group but did not differ between groups (23% vs. 19%; $P = 0.51$). External beam radiotherapy did reduce distant progression and recurrence-free survival (25).

Preliminary results from PIVOT have also become available since the evidence review was completed. PIVOT, conducted in the United States, included men with prostate cancer detected after the initiation of widespread PSA testing and, thus, included a much higher percentage of men with screen-detected prostate cancer. The trial randomly assigned 731 men aged 75 years or younger (mean age, 67 years) with a PSA level less than 50 μg/L (mean, 10 μg/L) and clinically localized prostate cancer to radical prostatectomy versus watchful waiting. One third of participants were black. On the basis of PSA level, Gleason score, and tumor stage, approximately 43% had low-risk tumors, 36% had intermediate-risk tumors, and 21% had high-risk tumors. After a median follow-up of 10 years, prostate cancer–specific or all-cause mortality did not statistically significantly differ between men treated with surgery versus observation (absolute risk reduction, 2.7% [CI, −1.3% to 6.2%] and 2.9% [CI, −4.1% to 10.3%], respectively). Subgroup analysis found that the effect of radical prostatectomy compared with observation for both overall and prostate cancer–specific mortality did not vary by patient characteristics (including age, race, health status, Charlson comorbidity index score, or Gleason score), but there was variation by PSA level and possibly tumor risk category. In men in the radical prostatectomy group with a PSA level greater than 10 μg/L at diagnosis, there was an absolute risk reduction of 7.2% (CI, 0.0% to 14.8%) and 13.2% (CI, 0.9% to 24.9%) for prostate cancer–specific and all-cause mortality, respectively, compared with men in the watchful waiting group. However, prostate cancer–specific or all-cause mortality was not reduced among men in the radical prostatectomy group with PSA levels of 10 μg/L or less or those with low-risk tumors, and potential (nonstatistically significant) increased mortality was suggested when compared with the watchful waiting group (12).

Harms of Screening and Treatment

False-positive PSA test results are common and vary depending on the PSA cutoff and frequency of screening. After 4 PSA tests, men in the screening group of the PLCO trial had a 12.9% cumulative risk for at least 1 false-positive result (defined as a PSA level greater than 4.0 μg/L and no prostate cancer diagnosis after 3 years) and a 5.5% risk for at least 1 biopsy due to a false-positive result (47). Men with false-positive PSA test results are more likely than control participants to worry specifically about prostate cancer, have a higher perceived risk for prostate cancer, and report problems with sexual function for up to 1 year after testing (48). In 1 study of men with false-positive PSA test results, 26% reported that they had experienced moderate to severe pain during biopsy; men with false-positive results were also more likely to have repeated PSA testing and additional biopsies during the 12 months after the initial negative biopsy (49). False-negative results also occur, and there is no PSA level that effectively rules out prostate cancer. This has, in part, led to recommendations for doing prostate biopsy at lower PSA thresholds than previously used in randomized screening trials (for example, <2.5 μg/L).

Harms of prostate biopsy reported by the Rotterdam center of the ERSPC trial include persistent hematospermia (50.4%), hematuria (22.6%), fever (3.5%), urine retention (0.4%), and hospitalization for signs of prostatitis

or urosepsis (0.5%) (50). The ProtecT study, an ongoing randomized, controlled trial evaluating the effectiveness and acceptability of treatments for men with PSA-detected, localized prostate cancer, found that 32% of men experienced pain; fever; blood in the urine, semen, or stool; infection; transient urinary difficulties; or other issues requiring clinician follow-up after prostate biopsy that they considered a "moderate or major problem." At 7 days after biopsy, 20% of men reported that they would consider a future biopsy a "moderate or major problem" and 1.4% of men were hospitalized for complications (6). Similar findings were reported at 30 days after biopsy in a U.S. study of older, predominately white male Medicare beneficiaries (51).

The high likelihood of false-positive results from the PSA test, coupled with its inability to distinguish indolent from aggressive tumors, means that a substantial number of men undergo biopsy and are overdiagnosed with and overtreated for prostate cancer. The number of men who have biopsies is directly related to the number of men having PSA testing, the threshold PSA level used to trigger a biopsy, and the interval between PSA tests. Estimates derived from the ERSPC and PLCO trials suggest overdiagnosis rates of 17% to 50% of prostate cancer cases detected by the PSA test (3, 52, 53). Overdiagnosis is of particular concern because, although these men cannot benefit from any associated treatment, they are still subject to the harms of a given therapy. Evidence indicates that nearly 90% of U.S. men diagnosed with clinically localized prostate cancer through PSA testing have early treatment (primarily radical prostatectomy and radiation therapy) (7, 8).

Radical prostatectomy is associated with a 20% increased absolute risk for urinary incontinence and a 30% increased absolute risk for erectile dysfunction compared with watchful waiting (that is, increased 20% above a median rate of 6% and 30% above a median rate of 45%, respectively) after 1 to 10 years (9, 10). Perioperative deaths or cardiovascular events occur in approximately 0.5% or 0.6% to 3% of patients, respectively (9, 10). Comparative data on outcomes using different surgical techniques are limited; 1 population-based observational cohort study using the SEER database and Medicare-linked data found that minimally invasive or robotic radical prostatectomy for prostate cancer was associated with higher risks for genitourinary complications, incontinence, and erectile dysfunction than open radical prostatectomy (54).

Radiation therapy is associated with a 17% absolute increase in risk for erectile dysfunction (that is, increased 17% above a median rate of 50%) and an increased risk for bowel dysfunction (for example, fecal urgency or incontinence) compared with watchful waiting after 1 to 10 years; the effect on bowel function is most pronounced in the first few months after treatment (9, 10).

Localized prostate cancer is not an FDA-approved indication for androgen deprivation therapy, and clinical outcomes for older men receiving this treatment for localized disease are worse than for those who are conservatively managed (55). Androgen deprivation therapy is associated with an increased risk for impotence compared with watchful waiting (absolute risk difference, 43%), as well as systemic effects, such as hot flashes and gynecomastia (9, 10). In advanced prostate cancer, androgen deprivation therapy may generate other serious harms, including diabetes, myocardial infarction, or coronary heart disease; however, these effects have not been well-studied in men treated for localized prostate cancer. A recent meta-analysis of 8 randomized, controlled trials in men with nonmetastatic high-risk prostate cancer found that androgen deprivation therapy was not associated with increased cardiac mortality (56).

Estimate of Magnitude of Net Benefit

All but 1 randomized trial has failed to demonstrate a reduction in prostate cancer deaths with the use of the PSA test, and several—including the PLCO trial—have suggested an increased risk in screened men, potentially due to harms associated with overdiagnosis and overtreatment. In a prespecified subgroup of men aged 55 to 69 years in the ERSPC trial, a small (0.09%) absolute reduction in prostate cancer deaths was seen after a median follow-up of 11 years. The time until any potential cancer-specific mortality benefit (should it exist) for PSA-based screening emerges is long (at least 9 to 10 years), and most men with prostate cancer die of causes other than prostate cancer (57). No prostate cancer screening study or randomized trial of treatment of screen-detected cancer has demonstrated a reduction in all-cause mortality through 14 years of follow-up.

The harms of PSA-based screening for prostate cancer include a high rate of false-positive results and accompanying negative psychological effects, high rate of complications associated with diagnostic biopsy, and—most important—a risk for overdiagnosis coupled with overtreatment. Depending on the method used, treatments for prostate cancer carry the risk for death, cardiovascular events, urinary incontinence, erectile dysfunction, and bowel dysfunction. Many of these harms are common and persistent. Given the propensity for physicians and patients to treat screen-detected cancer, limiting estimates of the harms of PSA testing to the harms of the blood test alone, without considering other diagnostic and treatment harms, does not reflect current clinical practice in the United States.

The mortality benefits of PSA-based prostate cancer screening through 11 years are, at best, small and potentially none, and the harms are moderate to substantial. Therefore, the USPSTF concludes with moderate certainty that the benefits of PSA-based screening for prostate cancer, as currently used and studied in randomized, controlled trials, do not outweigh the harms.

How Does Evidence Fit With Biological Understanding?

Prostate-specific antigen–based screening and subsequent treatment, as currently practiced in the United

States, presupposes that most asymptomatic prostate cancer cases will ultimately become clinically important and lead to poor health outcomes and that early treatment effectively reduces prostate cancer–specific and overall mortality. However, long-term, population-based cohort studies and randomized treatment trials of conservatively managed men with localized prostate cancer do not support this hypothesis. A review of the Connecticut Tumor Registry, which was initiated before the PSA screening era, examined the long-term probability of prostate cancer death among men (median age at diagnosis, 69 years) whose tumors were mostly incidentally identified at the time of transurethral resection or open surgery for benign prostatic hyperplasia. Men received observation alone or early or delayed androgen deprivation therapy. After 15 years of follow-up, the prostate cancer mortality rate was 18 deaths per 1000 person-years. For men with well-differentiated prostate cancer, it was 6 deaths per 1000 person-years; far more of these men had died of causes other than prostate cancer (75% vs. 7%) (58). An analysis of the SEER database after the widespread introduction of PSA-based screening examined the risk for death in men with localized prostate cancer who did not have initial attempted curative therapy. The 10-year prostate cancer mortality rate for well- or moderately differentiated tumors among men aged 66 to 69 years at diagnosis was 0% to 7%, depending on tumor stage, versus 0% to 22% for other causes. The relative proportion of deaths attributable to other causes compared with prostate cancer increased substantially with age at prostate cancer diagnosis (59). In the only randomized, controlled trial comparing early intervention versus watchful waiting that included men primarily detected by PSA testing, prostate cancer mortality at 12 years or more was infrequent (7%) and did not differ between men randomly assigned to surgery versus observation (12).

Update of Previous USPSTF Recommendation

This recommendation replaces the 2008 recommendation (38). Whereas the USPSTF previously recommended against PSA-based screening for prostate cancer in men aged 75 years or older and concluded that the evidence was insufficient to make a recommendation for younger men, the USPSTF now recommends against PSA-based screening for prostate cancer in all age groups.

Recommendations of Others

The American Urological Association recommends that PSA screening, in conjunction with a digital rectal examination, should be offered to asymptomatic men aged 40 years or older who wish to be screened, if estimated life expectancy is greater than 10 years (60). It is currently updating this guideline (61). The American Cancer Society emphasizes informed decision making for prostate cancer screening: Men at average risk should receive information beginning at age 50 years, and black men or men with a family history of prostate cancer should receive information at age 45 years (62). The American College of Preventive Medicine recommends that clinicians discuss the potential benefits and harms of PSA screening with men aged 50 years or older, consider their patients' preferences, and individualize screening decisions (63). The American Academy of Family Physicians is in the process of updating its guideline, and the American College of Physicians is currently developing a guidance statement on this topic.

From the U.S. Preventive Services Task Force, Rockville, Maryland.

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Annals of Internal Medicine

Appendix 1: U.S. Preventive Services Task Force

Members of the U.S. Preventive Services Task Force at the time this recommendation was finalized† are Virginia A. Moyer, MD, MPH, *Chair* (Baylor College of Medicine, Houston, Texas); Michael L. LeFevre, MD, MSPH, *Co-Vice Chair* (University of Missouri School of Medicine, Columbia, Missouri); Albert L. Siu, MD, MSPH, *Co-Vice Chair* (Mount Sinai School of Medicine, New York, and James J. Peters Veterans Affairs Medical Center, Bronx, New York); Linda Ciofu Baumann, PhD, RN (University of Wisconsin, Madison, Wisconsin); Kirsten Bibbins-Domingo, PhD, MD (University of California, San Francisco, San Francisco, California); Susan J. Curry, PhD (University of Iowa College of Public Health, Iowa City, Iowa); Mark Ebell, MD, MS (University of Georgia, Athens, Georgia); Glenn Flores, MD (University of Texas Southwestern, Dallas, Texas); Adelita Gonzales Cantu, RN, PhD (University of Texas Health Science Center, San Antonio, Texas); David C. Grossman, MD, MPH (Group Health Cooperative, Seattle, Washington); Jessica Herzstein, MD, MPH (Air Products, Allentown, Pennsylvania); Joy Melnikow, MD, MPH (University of California, Davis, Sacramento, California); Wanda K. Nicholson, MD, MPH, MBA (University of North Carolina School of Medicine, Chapel Hill, North Carolina); Douglas K. Owens, MD, MS (Stanford University, Stanford, California); Carolina Reyes, MD, MPH (Virginia Hospital Center, Arlington, Virginia); and Timothy J. Wilt, MD, MPH (University of Minnesota and Minneapolis Veterans Affairs Medical Center, Minneapolis, Minnesota). Former USPSTF members who contributed to the development of this recommendation include Ned Calonge, MD, MPH, and Rosanne Leipzig, MD, PhD.

† For a list of current Task Force members, visit www.uspreventiveservicestaskforce.org/members.htm.

Appendix 2: Assumptions and References Informing Table 3

Estimates of the number of prostate cancer deaths in screened and unscreened men are taken from the 11- and 13-year follow-up studies of the PLCO (23) and ERSPC (15) trials. False-positive rates for PSA tests are derived from the PLCO trial and the Finnish center of the ERSPC trial (47, 64). Information related to the harms of biopsy is derived from the work of Rosario and colleagues (6). The incidence of prostate cancer in a screened population is derived from the incidence seen in the screened group of the PLCO trial (23). Treatment rates for localized prostate cancer in the U.S. population are derived from the SEER program and the Cancer of the Prostate Strategic Urologic Research Endeavor registry (9, 10). Expected complication rates from prostatectomy and radiation therapy are derived from pooled estimates calculated in the evidence review done for the USPSTF (10).

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ACP American College of Physicians
Guidance Statements

CLINICAL GUIDELINE

Screening for Prostate Cancer: A Guidance Statement From the Clinical Guidelines Committee of the American College of Physicians

Amir Qaseem, MD, PhD, MHA; Michael J. Barry, MD; Thomas D. Denberg, MD, PhD; Douglas K. Owens, MD, MS; and Paul Shekelle, MD, PhD, for the Clinical Guidelines Committee of the American College of Physicians*

Description: Prostate cancer is an important health problem in men. It rarely causes death in men younger than 50 years; most deaths associated with it occur in men older than 75 years. The benefits of screening with the prostate-specific antigen (PSA) test are outweighed by the harms for most men. Prostate cancer never becomes clinically significant in a patient's lifetime in a considerable proportion of men with prostate cancer detected with the PSA test. They will receive no benefit and are subject to substantial harms from the treatment of prostate cancer. The American College of Physicians (ACP) developed this guidance statement for clinicians by assessing current prostate cancer screening guidelines developed by other organizations. ACP believes that it is more valuable to provide clinicians with a rigorous review of available guidelines rather than develop a new guideline on the same topic when several guidelines are available on a topic or when existing guidelines conflict. The purpose of this guidance statement is to critically review available guidelines to help guide internists and other clinicians in making decisions about screening for prostate cancer. The target patient population for this guidance statement is all adult men.

Methods: This guidance statement is derived from an appraisal of available guidelines on screening for prostate cancer. Authors searched the National Guideline Clearinghouse to identify prostate cancer screening guidelines in the United States and selected 4 developed by the American College of Preventive Medicine, American Cancer Society, American Urological Association, and U.S. Preventive Services Task Force. The AGREE II (Appraisal of Guidelines, Research and Evaluation in Europe) instrument was used to evaluate the guidelines.

Guidance Statement 1: *Guidance Statement 1: ACP recommends that clinicians inform men between the age of 50 and 69 years about the limited potential benefits and substantial harms of screening for prostate cancer. ACP recommends that clinicians base the decision to screen for prostate cancer using the prostate-specific antigen test on the risk for prostate cancer, a discussion of the benefits and harms of screening, the patient's general health and life expectancy, and patient preferences. ACP recommends that clinicians should not screen for prostate cancer using the prostate-specific antigen test in patients who do not express a clear preference for screening.*

Guidance Statement 2: *Guidance Statement 2: ACP recommends that clinicians should not screen for prostate cancer using the prostate-specific antigen test in average-risk men under the age of 50 years, men over the age of 69 years, or men with a life expectancy of less than 10 to 15 years.*

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For author affiliations, see end of text.

Although 1 in 6 men (16.7%) will receive a diagnosis of prostate cancer in their lifetime (1), only 2.9% will eventually die of the disease (2). The proportion of men who are diagnosed with prostate cancer but never have associated clinical symptoms is difficult to estimate, but it may range from 23% to 66% (3). Among cancer-related deaths in men, prostate cancer is the second-leading cause (4), representing 11.2% of such deaths (5). An estimated 2.3 million Americans have prostate cancer (5). In 2012, approximately 241 000 men are expected to be diagnosed with prostate cancer and 28 000 are expected to die of it (6).

The purpose of this guidance statement is to critically review the available guidelines developed in the United States to help guide internists and other clinicians in making decisions about screening for prostate cancer. The target patient population for this guidance statement is all adult men. The 2 tests generally used for screening and discussed in this guidance statement include the prostate-specific antigen (PSA) test and digital rectal examination (DRE). The PSA test is more sensitive than DRE, and no screening trials have evaluated the utility of DRE alone. Clinical trials of PSA-based screening have focused on ab-

See also:

Print
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* This paper, written by Amir Qaseem, MD, PhD, MHA; Michael J. Barry, MD; Thomas D. Denberg, MD, PhD; Douglas K. Owens, MD, MS; and Paul Shekelle, MD, PhD, was developed for the Clinical Guidelines Committee of the American College of Physicians. Individuals who served on the Clinical Guidelines Committee from initiation of the project until its approval were: Paul Shekelle, MD, PhD (*Chair*); Roger Chou, MD; Molly Cooke, MD; Paul Dallas, MD; Thomas D. Denberg, MD, PhD; Nick Fitterman, MD; Mary Ann Forciea, MD; Robert H. Hopkins Jr., MD; Linda L. Humphrey, MD, MPH; Tanveer P. Mir, MD; Douglas K. Owens, MD, MS; Holger J. Schünemann, MD, PhD; Donna E. Sweet, MD; David S. Weinberg, MD, MSc; and Timothy Wilt, MD, MPH. Approved by the ACP Board of Regents on 16 April 2012.
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solute PSA threshold levels to guide biopsy decisions. Although various strategies can be used to try to improve the diagnostic performance of the PSA test, such as PSA velocity (change in PSA over time), PSA density (PSA per unit volume of the prostate gland), or free PSA, these strategies have not been evaluated in clinical trials of screening and are not discussed in this guidance statement.

METHODS

When several guidelines are available on a topic or existing guidelines conflict, ACP believes that it is more useful to provide clinicians with a rigorous review of the available guidelines rather than develop a new guideline on the same topic. Thus, the ACP Clinical Guidelines Committee developed this guidance statement for clinicians by assessing current guidelines developed by other organizations on screening for prostate cancer.

We began by searching the National Guideline Clearinghouse for guidelines on screening for prostate cancer (August 2012). We reviewed the titles and abstracts of each document. We excluded those that were obviously restating guidelines from other organizations. We selected 4 prostate cancer screening guidelines developed in the United States: American College of Preventive Medicine (ACPM) (7), American Cancer Society (ACS) (8), American Urological Association (AUA) (9), and U.S. Preventive Services Task Force (USPSTF) (10). These guidelines were reviewed independently by 4 coauthors. We followed the AGREE II (Appraisal of Guidelines, Research and Evaluation in Europe) collaboration method to produce this guidance statement (11). The AGREE II instrument asks 23 questions in 6 domains: scope and purpose, stakeholder involvement, rigor of development, clarity and presentation, applicability, and editorial independence. The authors selected 1 guideline to calibrate their scores on the 6 domains of the AGREE II instrument. The authors then scored each guideline independently, and the scores were compared (**Table 1**). Although total quantitative scores varied, the qualitative assessment of guideline quality was consistent among the 4 reviewers; indeed, the overall rankings of the quality of the guidelines were similar.

Details of the ACP guidance statement development process can be found in ACP's methods paper (12).

SUMMARY AND EVALUATION OF REVIEWED GUIDELINES

ACPM (2008)

> ACPM concludes that there is insufficient evidence to recommend routine population screening with digital rectal exam or prostate-specific antigen.
>
> ACPM concludes that clinicians caring for men, especially African American men and those with a family history of prostate cancer, should provide information about potential benefits and risks of prostate cancer screening, and the limitations of current evidence for screening in order to maximize informed decision-making. While the usual age for prostate cancer screening is between 50-70 years in average risk men, it has been suggested that those who are at high risk may benefit from earlier screening beginning at age 45, while even higher risk men (those with two or more first-degree relatives with prostate cancer before age 65) should be screened at age 40.

Comments

The stated purpose of the ACPM guideline is to review the efficacy of DRE and the PSA test for prostate cancer screening. It includes a very helpful discussion on PSA screening criteria and cutoff PSA levels and acknowledges high false-positive and false-negative rates associated with the PSA test and weak evidence for DRE. The guideline emphasizes a shared decision-making approach for screening and discusses tools to support discussion with patients. However, many details about the literature review and guideline development process are not presented. In addition, the guideline was published before the PLCO (Prostate, Lung, Colorectal, and Ovarian) Cancer Screening Trial and ERSPC (European Randomized Study of Screening for Prostate Cancer) results were published. The guideline does not address the upper age limit for prostate screening or the issue of screening younger men in a high-risk group.

ACS (2010 Update)

> ACS recommends that asymptomatic men who have at least a 10-year life expectancy have an opportunity to make an informed decision with their health care provider about screening for prostate cancer after they receive information about the uncertainties, risks, and potential benefits associated with prostate cancer screening.
>
> ACS recommends that prostate cancer screening should not occur without an informed decision-making process. Men at average risk should receive this information beginning at age 50 years. Men in higher risk groups should receive this information before age 50 years. Men should either receive this information directly from their health care providers or be referred to reliable and culturally appropriate sources.

Comments

The stated goal of the ACS guideline is to focus on evidence related to the early detection of prostate cancer, test performance, harms of therapy for localized prostate cancer, and the importance of shared and informed decision making in prostate cancer screening. The ACS acknowledges the unclear role for DRE screening and recommends PSA screening with or without DRE, adding that the additional value of DRE is likely low. The guideline acknowledges the limitations of the evidence and describes a shared decision-making approach, which makes it very

Table 1. **Mean Guideline Scores and Scaled Domain Scores Across Domains of AGREE II Instrument***

Domains	ACS	AUA	USPSTF	ACPM
Scope and purpose				
1. The overall objective(s) of the guideline is (are) specifically described.	6	5	6	5
2. The health question(s) covered by the guideline is (are) specifically described.	6	6	6	5
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	6	5	7	4
Domain score	18	16	19	13
Scaled domain score, %	83	71	88	57
Stakeholder involvement				
4. The guideline development group includes individuals from all relevant professional groups.	5	5	4	2
5. The views and preferences of the target population (patients, public, etc.) have been sought.	3	2	4	2
6. The target users of the guideline are clearly defined.	3	6	6	2
Domain score	11	13	14	6
Scaled domain score, %	44	54	61	15
Rigor of development				
7. Systematic methods were used to search for evidence.	5	2	7	2
8. The criteria for selecting the evidence are clearly described.	4	1	7	2
9. The strengths and limitations of the body of evidence are clearly described.	4	2	7	2
10. The methods for formulating the recommendations are clearly described.	4	4	6	2
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	6	5	7	6
12. There is an explicit link between the recommendations and the supporting evidence.	5	4	7	3
13. The guideline has been externally reviewed by experts prior to its publication.	5	5	6	2
14. A procedure for updating the guideline is provided.	2	2	6	1
Domain score	35	24	51	18
Scaled domain score, %	56	33	90	21
Clarity of presentation				
15. The recommendations are specific and unambiguous.	7	5	7	6
16. The different options for management of the condition or health issue are clearly presented.	6	6	6	5
17. Key recommendations are easily identifiable.	6	6	7	5
Domain score	19	16	20	16
Scaled domain score, %	88	74	92	71
Applicability				
18. The guideline describes facilitators and barriers to its application.	6	2	4	3
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	6	2	4	6
20. The potential resource implications of applying the recommendations have been considered.	1	1	2	3
21. The guideline presents monitoring and/or auditing criteria.	1	2	2	2
Domain score	14	7	11	13
Scaled domain score, %	43	10	30	36
Editorial independence				
22. The views of the funding body have not influenced the content of the guideline.	2	3	6	2
23. Competing interests of guideline development group members have been recorded and addressed.	6	6	6	4
Domain score	8	9	12	6
Scaled domain score, %	50	54	81	31
Overall guideline assessment				
1. Rate the overall quality of this guideline.	5	3	6	3
2. I would recommend this guideline for use (please respond: yes, yes with modifications, or no).	4 yes	4 yes with modifications	2 yes; 2 yes with modifications	1 yes, 3 no

ACPM = American College of Preventive Medicine; ACS = American Cancer Society; AGREE = Appraisal of Guidelines, Research and Evaluation in Europe; AUA = American Urological Association; USPSTF = U.S. Preventive Services Task Force.

* Mean guideline scores across domains of the AGREE II instrument. Each question was rated on a Likert scale with a maximum of 7 points. The scores were averaged for each of the 4 reviewers. The scaled domain score is calculated as follows: (obtained score − minimum possible score) ÷ (maximum possible score − minimum possible score).

helpful for clinicians. It also has a clear cutoff age to start screening discussions with patients (age 50 years for average-risk men).

AUA (2009 Update)

AUA recommends that the decision to use PSA for the early detection of prostate cancer should be individualized. Patients should be informed of the known risks and the potential benefits.

AUA recommends that men who wish to be screened for prostate cancer should have both a PSA test and a DRE.

AUA recommends that early detection and risk assessment of prostate cancer should be offered to asymptomatic men 40 years of age or older who wish to be screened and have an estimated life expectancy of more than 10 years.

Comments

In addition to discussing the management and treatment of patients with prostate cancer, the goals of the AUA guideline are to help clinicians understand the evidence for using the PSA test to evaluate men at risk for prostate cancer and provide guidance about how to discuss the risks and benefits of early detection with patients. The guideline acknowledges that evidence is lacking about the proportion of clinically significant prostate cancer that is detected with PSA testing. The guideline emphasizes the sensitivity and specificity of PSA testing in addition to age-specific reference ranges that should be considered when evaluating the results for serum PSA. It discusses the association between elevated serum PSA levels with common prostatic diseases, such as prostatitis, benign prostatic hyperplasia, and prostate cancer. The guideline notes the harms of screening. The AUA's recommendation to begin baseline testing at age 40 years is not based on data from clinical trials. In addition, the guideline does not specify a threshold PSA level to initiate further evaluation, making this guideline challenging to implement. The AUA guideline focuses on PSA screening but suggests that the addition of DRE to PSA screening may enhance prostate cancer detection and, therefore, recommends DRE in addition to PSA tests.

USPSTF (2012 Update)

USPSTF recommends against PSA-based screening for prostate cancer.

Comments

The USPSTF recently updated its prostate cancer screening guideline in 2012. The purpose of the USPSTF guideline is to evaluate the evidence on the benefits and harms of detection and early treatment of prostate cancer to make recommendations about screening for prostate cancer using the PSA test. The guideline uses rigorous methods, evaluates evidence through a systematic literature review, and links the evidence and recommendations. The target population for the recommendation is all asymptomatic men regardless of age or risk factors. The guideline describes the primary benefit of prostate cancer screening being the reduction of deaths. It concluded that the benefits of PSA-based screening do not outweigh the harms and recommends against screening. The USPSTF states that physicians should not offer or order PSA screening unless they are prepared to engage in shared decision making that enables an informed choice by the patients with full understanding of the possible benefits and risk for harm. The harms of screening were identified as many false-positive results (80% when the PSA cutoff is between 2.5 and 4.0 μg/L); negative psychological effects, such as persistent worry; unnecessary biopsies; and overdiagnosis of tumors that may not become clinically significant in a patient's lifetime. The USPSTF also identified harms related to treatment of screen-detected cancer, such as surgery, radiation, and androgen-deprivation therapy. They also considered harms related to treatment of overdiagnosed cancer because the rate of treatment of screen-detected cancer is high. The USPSTF did not address use of DRE in the guideline.

Summary

In light of current evidence, making decisions about screening for prostate cancer is a complex issue. The 2012 USPSTF guideline concluded that the harms of prostate cancer screening outweigh the benefits for most men and recommended against screening using the PSA test. The other guidelines we evaluated concluded (at the time of the evidence review) that it is uncertain whether the benefits of routine screening using the PSA test outweigh the harms. In addition, all of the guidelines acknowledged that the benefits of early detection with the PSA test must be weighed against the serious harms, such as a false-positive rate of 70% for PSA levels greater than 4.0 μg/L (8), and the harms associated with treating men with cancer that would not have become clinically evident in their lifetime. The ACPM, ACS, and AUA guidelines recommend using a shared decision-making approach. However, the recommendations about shared decision making vary among the guidelines. The ACS and AUA recommend not to screen unless an informed decision-making approach has been used. The ACPM does not explicitly emphasize shared decision making to the same extent as the ACS and AUA. Clinicians should help men understand the potential benefits of early detection; the strengths and weaknesses of the various screening tests, such as the PSA test; and the risks of treating cancer that is detected by screening. Although the USPSTF does not recommend screening with the PSA test, it does suggest that men who opt to be screened should only do so after being fully informed of the benefits and harms. Studies have shown that up to one third of men screened for prostate cancer were unaware that they were being tested, and many men who were aware that they were tested do not receive an adequate discussion of the benefits and harms of screening (13–15).

The primary benefit of reduction in mortality rates from PSA-based screening was assessed by 2 higher-quality trials, ERSPC and PLCO (16, 17). The ERSPC study, which used various screening intervals, showed an absolute reduction in deaths due to prostate cancer in men between 55 and 69 years of age (17), and an additional 2-year follow-up confirmed a reduction in deaths due to prostate cancer in the screened group (18). In the PLCO study, there was no mortality benefit because more deaths occurred in the screened group (50 deaths) than in the control group (44 deaths), but this difference was not statistically significant (16). A similar trend was seen after 13 years of follow-up (19). Both the ERSPC and PLCO trials included mostly white men, and hence, the results from these studies may not be as applicable to nonwhite men. PIVOT (Prostate Cancer Intervention Versus Observation Trial) (20) assessed treatment by randomly assigning men

with local prostate cancer to radical prostatectomy or observation. Many men treated for prostate cancer were screened with the PSA test. The trial found that prostatectomy did not reduce overall or prostate cancer deaths after 12-year follow-up. However, in a subgroup analysis, men with PSA levels greater than 10 μg/L had a 13.2% reduction in all-cause mortality (hazard ratio, 0.67 [95% CI, 0.48 to 0.94]).

Clinically significant harms are associated with prostate cancer screening and treatment, including infections and urinary retention resulting from biopsies, overdiagnosis, overtreatment, and downstream harms and costs associated with overtreatment (21). False-positive results also lead to anxiety. Whether the harms associated with treatment can be reduced by more selective treatment of men with low-risk cancer is debatable. However, epidemiologic data indicate that nearly 90% of men with screen-detected cancer receive treatment aimed at a cure (such as prostatectomy and radiotherapy) (22, 23) rather than observation or active surveillance.

Although the evidence is unclear about which PSA levels should warrant a consideration of continuing with ongoing monitoring or biopsy, most of the guidelines we evaluated, as well as the PLCO study, used 4.0 μg/L as a threshold. Bacterial prostatitis or asymptomatic prostatic inflammation may cause the elevated PSA levels that generally return to baseline 6 to 8 weeks after symptoms resolve. This guidance statement recognizes that as many as 15% of men with PSA levels less than 4.0 μg/L will have prostate cancer on biopsy and as many as 15% of those with cancer will have high-grade cancer as assessed by pathology. However, although the ERSPC trial used PSA threshold levels that ranged between 2.5 and 4.0 μg/L, no evidence indicated that a biopsy-and-treat strategy based on lower PSA threshold levels (such as 3.0 μg/L or even 2.0 μg/L) will produce more benefits than higher thresholds and using a lower threshold will definitely result in more false-positive results. Therefore, on the basis of the limited evidence from current studies, it is reasonable to continue using the current most widely accepted PSA threshold level of 4.0 μg/L or greater.

Evidence is mixed on whether DRE is beneficial alone or in combination with PSA screening. Prostate screening using DRE was not addressed by the USPSTF, but it was recommended in addition to PSA screening in the AUA guideline and as an option to use with PSA testing in the ACS guideline. The sensitivity and specificity of DRE screening are dependent on the examiner, and therefore, considerable variability can occur with this test. The ACS suggests that DRE can be helpful in deciding whether to do a biopsy in men with PSA levels between 2.5 and 4.0 μg/L.

The current evidence does not provide direction about the frequency of screening with the PSA test. Although many clinicians in the United States screen annually, the PLCO trial, which screened annually, found no benefit. In the only trial to report a reduction in prostate cancer–specific mortality, most patients were screened every 4 years (range, 2 to 7 years) (17). Therefore, no evidence supports annual screening for prostate cancer. A recent modeling study showed that an aggressive screening strategy is associated with reduction in prostate cancer mortality but also results in major harms, such as unnecessary biopsies, diagnoses, and treatments (24). Screening older men (age >69 years) substantially increases overdiagnosis even though life expectancy is not affected in this age group. On the basis of the guidelines we reviewed, PSA levels of 2.5 μg/L or greater may warrant annual evaluation in men who seek early diagnosis.

Asymptomatic men older than 75 years or those who have a life expectancy less than 10 years should not be offered prostate cancer screening in light of the substantial harms associated with prostate cancer screening and treatment relative to questionable benefits.

Guidance Statements

Guidance Statement 1: ACP recommends that clinicians inform men between the age of 50 and 69 years about the limited potential benefits and substantial harms of screening for prostate cancer. ACP recommends that clinicians base the decision to screen for prostate cancer using the prostate-specific antigen test on the risk for prostate cancer, a discussion of the benefits and harms of screening, the patient's general health and life expectancy, and patient preferences. ACP recommends that clinicians should not screen for prostate cancer using the prostate-specific antigen test in patients who do not express a clear preference for screening.

Benefits and Harms of Screening (PSA Test and DRE)

The modest potential mortality benefit in 1 prostate cancer screening trial with the PSA test was limited to men between the age of 55 and 69 years. Data were insufficient to reach a conclusion about the benefits or harms of screening in men aged 50 to 54 years. However, because this group has a longer life expectancy, they have more potential for long-term net benefit. The ERSPC study, which screened men mostly with the PSA test, showed that 1410 men would need to be screened to prevent 1 death from prostate cancer (17). Evidence for the benefit of DRE screening is limited, and the PLCO trial, which included both PSA testing and DRE, showed no benefit. As far as mortality benefit is concerned, the evidence is inconsistent about whether screening reduces cancer-related death, and any absolute mortality risk reduction is probably small to none.

The harms of prostate cancer screening are substantial and include false alarms (suggesting that a patient may have cancer when he does not) related to high false-positive rates associated with DRE and especially the PSA test, overdiagnosis (that is, detecting cancer that will not cause future morbidity and mortality), high false-negative rates, anxiety, and discomfort. Positive screening results may lead

Table 2. **Freely Available Decision Aids for Prostate Cancer Screening**

Developer	Web Site
American Cancer Society	www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-024618.pdf
American Society of Clinical Oncology	www.asco.org/ASCOv2/Department%20Content/Cancer%20Policy%20and%20Clinical%20Affairs/Downloads/Guideline%20Tools%20and%20Resources/PSA/PSA%20PCO%20Decision%20Aid%207.16.12.pdf
The Prostate Cancer Research Foundation and European Randomized Study of Screening for Prostate Cancer	www.prostatecancer-riskcalculator.com
Mayo Clinic	www.mayoclinic.com/health/prostate-cancer/HQ01273

to further testing, such as biopsies, which not only can be painful but can also lead to complications, such as infections, as well as overtreatment and the harms associated with it. In addition, currently available treatments are associated with harms, such as urinary, gastrointestinal, and sexual problems, as well as potential cardiovascular events and death. Data from PIVOT (20) showed that men who had radical prostatectomy had an 11% increased risk for urinary incontinence and a 37% increased risk for erectile dysfunction. Harms specific to DRE include discomfort and rectal bleeding.

Shared Decision-Making Approach

Clinicians should not screen for prostate cancer in men who do not wish to make the screening decision or do not express a clear preference about screening. However, some men would still prefer to be screened because they may put more value on the possible small benefit and less value on the harms. In these circumstances, shared decision making is important in making choices about prostate cancer screening. Clinicians should elicit patient preferences for screening during the shared decision-making process and document them in the medical record. It is important to educate the patient about the following points and document the conversation in the medical record:

1. Prostate cancer screening with the PSA test is controversial.

2. Screening with the PSA test can detect prostate cancer, but for most men, the chances of harm from screening with the PSA test outweigh the chances of benefit.

3. A small number of prostate cancer cases are serious and can cause death; however, the vast majority of prostate cancer is slow-growing and does not cause death.

4. Most men who choose not to do PSA testing will not be diagnosed with prostate cancer and will die of something else.

5. Patients who choose PSA testing are much more likely than those who decline PSA testing to be diagnosed with prostate cancer.

6. The PSA test often does not distinguish between serious cancer and nonserious cancer. However, men with markedly elevated PSA levels (>10 μg/L) may have a reduced chance of dying from prostate cancer by having surgical treatment.

7. The small potential benefit of prostate cancer screening corresponds to preventing, at most, 1 death caused by prostate cancer per 1000 men screened after 11 years of follow-up.

8. There are many potential harms of screening. There may be problems in interpreting test results: The PSA test result may be high because of an enlarged prostate but not because of cancer, or it may be low even though cancer is present. Prostate biopsy, if needed is also not free from risk. It involves multiple needles being inserted into the prostate under local anesthesia, and there is risk for infection or clinically significant bleeding and hospitalization (1.4%). If cancer is diagnosed, it will often be treated with surgery or radiation, which are associated with risks. There is a small risk for death with surgery, loss of sexual function (approximately 37% higher risk), and loss of control of urination (approximately 11% higher risk) compared with no surgery. These risks may vary depending on patient and surgeon characteristics and treatment method.

9. The PSA test is not "just a blood test." It is a test that can open the door to more testing and treatment that a man may not actually want and that may actually harm him. A man's chances of being harmed are much greater than his chances of benefiting from the PSA test. Thus, each man should have the opportunity to decide for himself whether to have the PSA screening test.

10. Studies are ongoing, so clinicians expect to learn more about the benefits and harms of screening, and recommendations may change over time. Men are also welcome to change their minds at any time by asking for screening that they have previously declined or discontinue screening that they have previously requested.

Although ACP did not evaluate the evidence on the reliability, validity, or benefits of using available decision aids, some examples are listed in **Table 2**.

It is important for clinicians to convey to patients who may want to be screened that evidence indicates, at best, small benefits as well as substantial harms. Men who do not have a clear preference for screening should not be screened, and this should be documented. Clinicians should help men judge the balance of benefits and harms and discuss whether the harms outweigh the potential reduction in prostate cancer mortality in their particular cases. To frame the discussion, clinicians can inform patients that the PSA test will increase their lifetime risk for prostate cancer from approximately 9% to 16% (5, 25). Currently, the tradeoff between harms and benefits beyond

Figure. **The American College of Physicians guidance statement on screening for prostate cancer.**

ACP
American College of Physicians
Guidance Statements

Summary of the American College of Physicians Guidance Statement on Screening for Prostate Cancer

Disease or Condition	Prostate cancer
Target Audience	Internists, family physicians, other clinicians
Target Patient Population	All men
Screening Tests	PSA and DRE
Interventions	Strategies to manage prostate cancer
Outcomes	Mortality and morbidity
Indications for Discussing Screening	Men between the age of 50 and 69 y Earlier age in men who are at increased risk for prostate cancer (African American race and a first-degree relative [father or brother] diagnosed with prostate cancer, especially before age 65 y)
Frequency of Screening	No clear evidence guides the periodicity or frequency of screening No clear evidence that PSA screening more frequently than every 4 y produces any additional benefit PSA levels of 2.5 μg/L or greater may warrant yearly evaluation
Benefits of Screening	Reduction in mortality
Harms of Screening	False alarms related to number of high false-positives associated with DRE and especially PSA High false-negative rates Overdiagnosis (detection of cancer that is not destined to cause future morbidity and mortality) Overtreatment and associated harms, including bleeding, pain, and hospitalization Anxiety and discomfort Positive screening results may lead to further testing, such as biopsies, which not only can be painful but can also lead to complications, such as infections
Recommendations	*Guidance Statement 1: ACP recommends that clinicians inform men between the age of 50 and 69 years about the limited potential benefits and substantial harms of screening for prostate cancer. ACP recommends that clinicians base the decision to screen for prostate cancer using the prostate-specific antigen test on the risk for prostate cancer, a discussion of the benefits and harms of screening, the patient's general health and life expectancy, and patient preferences. ACP recommends that clinicians should not screen for prostate cancer using the prostate-specific antigen test in patients who do not express a clear preference for screening.* *Guidance Statement 2: ACP recommends that clinicians should not screen for prostate cancer using the prostate-specific antigen test in average-risk men under the age of 50 years, men over the age of 69 years, or men with a life expectancy of less than 10 to 15 years.*
Talking Points With Patients	Prostate cancer screening with the PSA test is controversial. PSA screening can detect prostate cancer, but for most men, the chances of harm from screening with the PSA test outweigh the chances of benefit. A small number of prostate cancer cases are serious and can cause death; however, the vast majority of prostate cancer is slow-growing and does not cause death. Most men who choose not to do PSA testing will not be diagnosed with prostate cancer and will die of something else. Patients who choose PSA testing are much more likely than those who decline PSA testing to be diagnosed with prostate cancer. The PSA test often does not distinguish between cancer cases that are serious and those cases that are not serious. However, men with markedly elevated PSA levels (>10 μg/L) may have a reduced chance of dying from prostate cancer by having surgical treatment. The small potential benefit of prostate cancer screening corresponds to preventing, at most, 1 death caused by prostate cancer per 1000 men screened after 11 y of follow-up. The potential harms of screening include: Problems interpreting test results: The PSA test result may be high because of an enlarged prostate but not because of cancer, or it may be low even though cancer is present. If a prostate biopsy is needed, it, too, is not free from risk—the biopsy involves multiple needles being inserted into the prostate under local anesthesia, and there is a risk for infection or significant bleeding as well as risk for hospitalization (1.4%). If cancer is diagnosed, it will often be treated with surgery or radiation, which are associated with risks. There is a small risk for death with surgery, loss of sexual function (approximately 37% higher risk), and loss of control of urination (approximately 11% higher risk) compared with no surgery. These risks may vary depending on patient and surgeon characteristics and treatment method. The PSA test is not "just a blood test." It is a test that can open the door to more testing and treatment that a man may not actually want and that may actually harm him. A man's chances of being harmed are much greater than his chances of benefiting from the PSA test. Thus, each man should have the opportunity to decide for himself whether to have the PSA screening test. Studies are ongoing, so clinicians expect to learn more about the benefits and harms of screening, and recommendations may change over time. Men are also welcome to change their minds at any time by asking for screening that they have previously declined or discontinue screening that they have previously requested.

ACP = American College of Physicians; DRE = digital rectal examination; PSA = prostate-specific antigen.

11 to 13 years of follow-up is unknown. Alternatively, although 3 in 100 men will die of prostate cancer (or 5 in 100 for African American men), this means that 97 in 100 men (or 95 in 100 African American men) will die of something else. Finally, although some men may avoid pain and discomfort commonly associated with advanced disease, this must be balanced against the possibility of incontinence, erectile dysfunction, and other side effects that result from certain forms of aggressive treatment.

The goal of screening for any disease is to identify an undiagnosed condition for which an effective treatment is available, and timely treatment can lead to improved clinical outcomes. Although the best treatment approach for prostate cancer is unknown, current management for prostate cancer includes active surveillance, radical prostatectomy, external beam radiation therapy, and brachytherapy. Research is needed to better identify cancer that is more likely to benefit from curative treatments, in which case, benefits are more likely to outweigh harms.

High-Risk Patients

Screening in high-risk men has not been demonstrated to be associated with different outcomes than screening in average-risk men. Risks for prostate cancer include African American race and a first-degree relative diagnosed with prostate cancer, especially before age 65 years. Patients with such risks should receive information about the uncertainties, risks, and potential benefits associated with prostate cancer screening beginning at age 45 years. Shared decision making is important in making choices about prostate cancer screening in high-risk men as well. Men at appreciably higher risk (multiple family members diagnosed with prostate cancer before age 65 years) should receive this information beginning at age 40 years.

Frequency of Screening

Currently, no clear evidence is available to guide decisions about the periodicity or frequency of the evaluation of risk for prostate cancer or discussion about the benefits and harms. Considering the harms of screening and modest mortality benefit, increasing the interval between screening tests may reduce harms (10). The PLCO trial, which screened annually, found no benefit, whereas the ERSPC trial, in which most participants were screened every 4 years (range, 2 to 7 years), did find benefit, suggesting that longer intervals may be indicated.

Guidance Statement 2: ACP recommends that clinicians should not screen for prostate cancer using the prostate-specific antigen test in average-risk men under the age of 50 years, men over the age of 69 years, or men with a life expectancy of less than 10 to 15 years.

Increasing age or the presence of a chronic comorbid illness that affects life expectancy substantially limits the potential benefits of prostate cancer screening compared with harms. Evidence presented in the guidelines shows substantial harms associated with prostate cancer screening and treatment relative to questionable benefits. Any benefit is even smaller in men older than 69 years because the cancer may not become clinically significant in a person's lifetime. For men younger than 50 years, the harms, such as erectile dysfunction and urinary incontinence, carry even more weight relative to any potential benefit. Hence, the harms of screening for prostate cancer outweigh the benefits in average-risk men younger than 50 years, men older than 69 years, or men who have a life expectancy less than 10 to 15 years. Therefore, clinicians should not screen men younger than 50 years, those aged 70 years or older, or men with substantial comorbid conditions and a life expectancy less than 10 to 15 years.

The **Figure** summarizes the guidance statements and clinical considerations for prostate cancer screening.

ACP High-Value Care Advice

High-value care reflects care for which the benefits are likely to outweigh the harms and costs associated with delivering such care. Screening with the PSA test is low-value care. The value of screening for prostate cancer in most cases is low, given that the chances of harm with screening outweigh the chances of benefit for most men and that the direct and indirect costs associated with biopsy, repeated testing, aggressive therapy, patient anxiety, and missed work are significant.

From the American College of Physicians, Philadelphia, Pennsylvania; Veterans Affairs Palo Alto Health Care System, Palo Alto, California; Massachusetts General Hospital, Boston, Massachusetts; West Los Angeles Veterans Affairs Medical Center, Los Angeles, California; and Harvard Vanguard Medical Associates, Auburndale, Massachusetts.

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Requests for Single Reprints: Amir Qaseem, MD, PhD, MHA, American College of Physicians, 190 N. Independence Mall West, Philadelphia, PA 19106; e-mail, aqaseem@acponline.org.

Current author addresses and author contributions are available at www.annals.org.

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Current Author Addresses: Dr. Qaseem: 190 N. Independence Mall West, Philadelphia, PA 19106.
Dr. Owens: 117 Encina Commons, Stanford, CA 94305.
Dr. Barry: 50 Staniford Street, 9th Floor, Boston, MA 02114.
Dr. Denberg: 275 Grove Street, Auburndale, MA 02466.
Dr. Shekelle: 11301 Wilshire Boulevard, Los Angeles, CA 90073.

Author Contributions: Conception and design: A. Qaseem, M.J. Barry, T.D. Denberg, D.K. Owens, P. Shekelle.
Analysis and interpretation of the data: A. Qaseem, M.J. Barry, T.D. Denberg, D.K. Owens.
Drafting of the article: A. Qaseem, T.D. Denberg.
Critical revision for important intellectual content: A. Qaseem, M.J. Barry, T.D. Denberg, D.K. Owens, P. Shekelle.
Final approval of the article: A. Qaseem, M.J. Barry, T.D. Denberg, D.K. Owens, P. Shekelle.
Provision of study materials or patients: A. Qaseem.
Statistical expertise: A. Qaseem.
Administrative, technical, or logistic support: A. Qaseem.
Collection and assembly of data: A. Qaseem, M.J. Barry.

AACU
American Association of Clinical Urologists, Inc.

What You Need to Know to Have an Informed Discussion Regarding The Early Detection of Prostate Cancer: Information for Patients and Medical Healthcare Providers

The American Association of Clinical Urologists (AACU) strongly supports and encourages a dialogue and discussion regarding the risks and benefits of screening for the Early Detection of Prostate Cancer. This brief letter will outline some of the key facts that you will need, in order to have this important and potentially life-saving discussion.

Unfortunately, the recent United States Preventive Services Task Force (USPSTF) recommendation downgrading the prostate specific antigen (PSA) test is being simply reduced to the practice of non-screening by physicians and the acceptance of this non-screening approach by many patients. The USPSTF recommendation did not include guidance regarding meaningful discussion or a dialogue between patients and providers. Instead, men are being placed at risk due to lack of discussion and understanding of the important issues. It would be unfortunate to return to the pre-PSA era when 25% of men with newly diagnosed prostate cancer were found to have cancer already spread beyond the prostate (i.e. metastatic and incurable), compared to todays' rate of less than 5%! Furthermore, the USPSTF recommendation downplayed the impact of prostate cancer mortality. Men do die from prostate cancer; it is the second leading cause of male cancer deaths, and evidence supports that screening does save lives. Recently, the American College of Physicians released a statement suggesting that physicians inform men between 50-69 years about the limited potential benefits and substantial harms of screening for prostate cancer. They further recommend that clinicians base the decision to screen for prostate cancer using the PSA test on the risk for prostate cancer, a discussion of the benefits and harms of screening, the patient's general health and life expectancy and patient preferences. None of the recommendations would argue against a discussion regarding screening; however, the AACU is concerned that this discussion is currently not being offered and physicians are simply accepting a recommendation against the use of PSA for the early detection of prostate cancer.

Here are some very important thoughts, facts and concerns you should be aware of regarding the early detection of prostate cancer that you will need to help make the appropriate decision regarding PSA screening:

The United State Preventive Services Task Force (USPSTF) reviews screening tests. They look at and review literature to make a decision. They look at the number of lives screened to save one life, the harms of the screening test, the outcome of screening (i.e. the treatment of the disease) and risks benefits of those therapies. No urology experts were part of the USPSTF, and although comments from the urological community were solicited after the document was prepared, no changes were incorporated. Urologists are traditionally the experts in prostate cancer care from diagnosis through treatment. The Urological Community feels that input through such experts during the drafting of this document would have benefited the community of patients and health care teams.

1) The literature reviewed by the USPSTF was only the published articles that were available at the time that the recommendation was drafted; however, subsequent literature and studies showing a better ratio of lives "screened to saved" were reported after the task force had made its review and were not included in its recommendation.

2) The studies that the USPSTF did review and the data therein has been the source of great controversy among experts, many of whom call into question the methodology and the implication of the data. A recent article (Etzioni R., et al – Med Care 2013 Apr; 51 (4):295-300)

reviews the limitations of basing screening policies on screening trials, with particular focus on the data reviewed by the US Preventive Services Task Force.

3) The body of literature reviewed regarding the side effects of prostate cancer treatment was prior to more modern therapies with improved benefits, and less risks.

4) The review of the literature failed to include the current urological data on "Active Surveillance" protocols and understanding of prostate cancer behavior. The review made assumptions that once a diagnosis of cancer was made, then it would automatically lead to treatment, which is not entirely true today, as urologists have a better understanding of prostate cancer behavior.

5) Urologists have long understood the imperfections of PSA and its value in early detection. Men who have a history of prior PSA data should not abandon that data. No recommendations are made with regard to this issue as we still lack sufficient data in this area.

6) A more recently published study in the British Medical Journal contradicts the US Preventive Services Task Force findings with data from a long running prostate cancer screening study of 21,277 men using PSA. The Malmo Study data suggests nearly half of all deaths from prostate cancer can be predicted before age 50, emphasizing the importance of screening men under the age of 50 with PSA.

7) The dynamics of the early detection of prostate cancer are constantly being reviewed and reshaped. What should really be considered is not the test, but what is done with the information obtained from the test. The urological community is well versed in this discussion. Don't abandon your ability to have a potentially life saving discussion with your healthcare provider regarding early detection and PSA use.

8) PSA is not a perfect cancer test; far from it, yet its value in early detection is still worth a very important discussion, one that patients and their health care team need to have. Please do not forgo the opportunity to have this discussion. If you are simply hearing that physicians do not recommend that you obtain a PSA or a digital rectal exam, then you are not hearing the entire debate.

The AACU encourages men to continue to be active in achieving good health through appropriate prevention and intervention strategies. We believe that the early detection of prostate cancer with PSA testing continues to offer value with benefits and lives saved. Make certain you have a discussion regarding the early detection of prostate cancer, and continue to be proactive in your own healthcare.

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ARTICLE

An Empirical Evaluation of Guidelines on Prostate-specific Antigen Velocity in Prostate Cancer Detection

Andrew J. Vickers, Cathee Till, Catherine M. Tangen, Hans Lilja, Ian M. Thompson

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Correspondence to: Andrew J. Vickers, PhD, Department of Epidemiology and Biostatistics, Memorial Sloan-Kettering Cancer Center, 307 E. 63rd St, New York, NY 10021 (e-mail: vickersa@mskcc.org).

Background The National Comprehensive Cancer Network and American Urological Association guidelines on early detection of prostate cancer recommend biopsy on the basis of high prostate-specific antigen (PSA) velocity, even in the absence of other indications such as an elevated PSA or a positive digital rectal exam (DRE).

Methods To evaluate the current guideline, we compared the area under the curve of a multivariable model for prostate cancer including age, PSA, DRE, family history, and prior biopsy, with and without PSA velocity, in 5519 men undergoing biopsy, regardless of clinical indication, in the control arm of the Prostate Cancer Prevention Trial. We also evaluated the clinical implications of using PSA velocity cut points to determine biopsy in men with low PSA and negative DRE in terms of additional cancers found and unnecessary biopsies conducted. All statistical tests were two-sided.

Results Incorporation of PSA velocity led to a very small increase in area under the curve from 0.702 to 0.709. Improvements in predictive accuracy were smaller for the endpoints of high-grade cancer (Gleason score of 7 or greater) and clinically significant cancer (Epstein criteria). Biopsying men with high PSA velocity but no other indication would lead to a large number of additional biopsies, with close to one in seven men being biopsied. PSA cut points with a comparable specificity to PSA velocity cut points had a higher sensitivity (23% vs 19%), particularly for high-grade (41% vs 25%) and clinically significant (32% vs 22%) disease. These findings were robust to the method of calculating PSA velocity.

Conclusions We found no evidence to support the recommendation that men with high PSA velocity should be biopsied in the absence of other indications; this measure should not be included in practice guidelines.

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Practice guidelines produced by expert committees are generally presumed to constitute distillations of the best published evidence. There is good reason to believe, however, that many guidelines are not as evidence based as they might be. Burgers et al. (1) reviewed 32 oncology guidelines using a validated guidelines assessment instrument. The mean score given to the guidelines was only 42 of a total of 100 for "rigor of development." The means for individual items in the rigor of development domain, for example, "systematic methods used to search for evidence," "explicit link between the recommendations and the supporting evidence," and "clear description of criteria used to select evidence," were below 50% for all but one item (1).

Close examination of prostate cancer guidelines, such as those by the National Comprehensive Cancer Network (NCCN) (2), reveals that many aspects of these guidelines are based on evidence. The recent results of the European Randomized Trial of Prostate Cancer Screening (3) give qualified support for prostate cancer screening; there is also clear evidence supporting the use of prostate-specific antigen (PSA) (4) and free PSA (5) to identify cancer, the exclusion of younger (6) and older men (7,8) from screening, and differential recommendations for African Americans and those with a family history of prostate cancer (9).

However, one particular aspect of the guidelines stands out with respect to its evidentiary base, which is the use of PSA velocity. The NCCN guidelines state that men with a high PSA velocity (rate of change of PSA level)—greater than 0.35 ng mL^{-1} y^{-1}—should consider biopsy even if absolute level of PSA is very low. The guidelines cite Carter et al. (10), who reported an association between PSA velocity and a diagnosis of fatal prostate cancer approximately 10–15 years subsequently. However, it is unclear why a marker that predicts aggressive prostate cancer many years in the future should be used to suggest immediate biopsy to patients. Moreover, PSA velocity was not demonstrated to add predictive accuracy to PSA alone. As such, the apparent predictive value of PSA velocity might simply reflect that PSA and PSA velocity are highly collinear—reported correlations are as high as 0.93 (11)—and that PSA itself is highly predictive of advanced prostate cancer (12). In addition, the cut point of

0.35 ng mL^{-1} y^{-1} appears to have been based on visual inspection of the receiver operating characteristics (ROC) curve: "[it] could be one reasonable choice—among others—to balance sensitivity and specificity for detection of life-threatening cancer" (10). PSA velocity is also included in the American Urological Association (AUA) PSA Best Practice Statement (13), albeit with a disclaimer regarding whether it adds predictive value to PSA alone (13). Similarly to the NCCN guidelines, the AUA states that a PSA velocity threshold of 0.4 ng mL^{-1} y^{-1} may improve prostate cancer detection for men with low PSA levels.

The problem with evaluating a recommendation to biopsy men with low PSA on the basis of a high PSA velocity is that of finding a suitable dataset, because only men with a high PSA are usually biopsied. The obvious exception is the Prostate Cancer Prevention Trial (PCPT), in which men received an end-of-study biopsy irrespective of PSA. Because men in the PCPT received regular PSA tests, excellent PSA data are available. As such, the PCPT provides a perfect test case for PSA velocity. In a previous report, we briefly described analyses of PSA velocity in the PCPT (9); herein we report an extensive set of analyses to investigate the clinical value of PSA velocity for prostate cancer detection in men otherwise without an indication for biopsy.

Methods

The methods and results of the PCPT have been previously published (14,15). In brief, men aged 55 years and older, with no previous prostate cancer diagnosis, normal digital rectal exam (DRE), and baseline PSA of 3.0 ng/mL or less were randomly assigned to finasteride or placebo for 7 years. Men were followed with yearly PSA tests, with biopsy recommended for men with PSA higher than 4.0 ng/mL (adjusted in the finasteride arm to take account of treatment-related reductions in PSA). After 7 years of therapy, all men who were not diagnosed with prostate cancer were asked to consent to an end-of-study biopsy. This dataset includes 5652 men from the placebo arm of the PCPT who underwent biopsy and had a PSA available and DRE performed within the year before the biopsy. There were missing data on one or more predictors for 133 men, leaving 5519 participants for analysis. For men who had more than one biopsy during the PCPT, only the last biopsy was used here.

Statistical Analyses

Our initial set of hypotheses concerned the marginal predictive accuracy of PSA velocity. We first created a logistic regression model using standard predictors for prostate cancer on biopsy, including age (modeled continuously), log PSA at biopsy (modeled continuously), family history of prostate cancer (yes/no), DRE (yes/no), and whether the patient had a prior prostate biopsy (yes/no). We used ROC curve analyses and calculated the area under the ROC curve (AUC) using fourfold cross-validation. AUC is a measure of the predictive accuracy of a marker or model and is scaled from 0.5 (no better than chance) to 1 (a perfect predictor). We then compared the AUC value with that of a statistical model including these predictors plus PSA velocity, calculated by linear regression of time on all log PSA values before biopsy. We also compared a model with only log PSA with one with both log PSA and PSA velocity. On the grounds that PSA velocity might differentially improve the detection of more aggressive cancers, we repeated this analysis defining a biopsy as positive only if the Gleason score is 7–10. Because some critics have suggested that cancers found on the PCPT end-of-study biopsy were small and not clinically significant, we also modeled "clinically significant" prostate cancer as an outcome, based on the "Epstein" criteria (16). Cancer was defined as clinically significant if any of the following applied: clinical stage greater than T1c, PSA density at least 0.15 ng mL^{-1} g^{-1}, Gleason score of at least 7, tumor in three or more cores, or at least one core with more than 50% cancer involvement. For the analysis of high-grade disease, low-grade tumors were categorized along with no cancer; comparably, in the analysis of clinically significant disease, cancers not meeting the criteria were placed in the same category as benign biopsy.

PSA velocity can be calculated in various ways, with differences as to the method of calculation (eg, log transformed or untransformed PSA values), the PSA values entered (eg, all values or just those within a certain time frame), and the patients eligible (eg, all patients or only those with a certain minimum number of PSA values over a certain minimum period of time). To be as comprehensive as possible, we repeated analyses with alternate methods of calculating PSA velocity.

CONTEXTS AND CAVEATS

Prior knowledge

Some guidelines for early detection of prostate cancer recommend biopsy on the basis of high prostate-specific antigen (PSA) velocity (rate of change of PSA level), even in the absence of elevated PSA levels or positive digital rectal exam (DRE). However, the clinical value of PSA velocity for prostate cancer detection in men without other indications for biopsy is unknown.

Study design

The predictive value of PSA velocity, adjusting for age, PSA levels, DRE, family history, and prior biopsy, was assessed for 5519 men in the placebo arm of the Prostate Cancer Prevention Trial, in which men received an end-of-study biopsy regardless of clinical indication.

Contribution

PSA velocity added little to the predictive accuracy of high PSA levels or positive DRE and would substantially increase the number of men recommended for a biopsy. The authors found no evidence to support prostate biopsy in men with high PSA velocity in the absence of other indications.

Implications

Implementation of PSA velocity as a guideline would be unlikely to improve patient outcomes and would lead to a large number of unnecessary biopsies.

Limitations

There might be better methods to calculate PSA velocity that could improve predictive accuracy. The cohort was not followed until death and some differences may emerge on very long-term follow-up.

From the Editors

As a direct evaluation of the NCCN and AUA guidelines, we evaluated the positive predictive value of various PSA velocity cut points in a subset of men with low PSA. To be comprehensive, we used three different PSA velocity cut points (0.35, 0.5, and 0.75 ng mL^{-1} y^{-1}) and two different definitions of low PSA (<4 and <2.5 ng/mL). Given that PSA velocity is strongly associated with PSA values, and PSA is associated with cancer risk, we thought it likely that the risk of cancer in men with low PSA would be higher above particular PSA velocity thresholds than below. Accordingly, we chose some reasonable PSA cut points to compare with PSA velocity cut points. If a PSA cut point could provide comparable sensitivity and specificity to a PSA velocity cut point in the subset of men with low PSA, there would be little rationale for what can be a time-consuming and complex calculation of PSA velocity. For this analysis, we calculated PSA velocity using linear regression on untransformed PSA values 2 years before biopsy. Our rationale for restricting the analyses to the most recent PSA values was twofold. First, restricting the analyses in this way reflects the NCCN guidelines themselves, which state that "measurement should be made on at least three consecutive specimens drawn over at least an 18–24 month interval" and that "longer time periods . . . decrease predictive power" (2). A similar statement is made in the AUA guidelines. Second, if the period were not restricted, very few men would meet the criteria for high PSA velocity but low PSA. Almost 90% of the men in our study cohort had a biopsy after 7 years on study. To have a PSA velocity of 0.35 ng mL^{-1} y^{-1} or more for 7 years but a final PSA of at least 2.5 ng/mL, participants would have to have a starting PSA of 0.05 ng/mL, which is extremely rare in men of screening age. All statistical tests were two-sided. All analyses were conducted using SAS version 9.

Results

Men with cancer were slightly older than those with negative biopsies, were more likely to be African American, and to have a family history of prostate cancer. They were also more likely to have been biopsied in an earlier round of screening (Table 1). Although most cancers had a Gleason score 6 or below (78%), only a minority (19%) met the Epstein criteria (16) for indolent disease (Table 2). Approximately one quarter of cancers could not be categorized by the Epstein criteria (16) because of inadequate pathological information. There is strong evidence of an association between PSA velocity and biopsy outcome ($P < .001$ by χ^2).

When PSA velocity was added to a multivariable prediction model for prostate biopsy outcome, the strong associations seen on univariate analyses were reduced. Odds ratios were moderate, and only a minority of PSA definitions were independently predictive (Table 3). All analyses were repeated using raw PSA values (ie, without log transformation), but this led to decreases in predictive value.

Table 1. Characteristics of the study cohort*

Characteristic	All (N = 5519), No. (%)	Biopsy negative (N = 4308), No. (%)	Biopsy positive (N = 1211), No. (%)	*P*
Family history of prostate cancer, No. (%)	920 (17)	668 (16)	252 (21)	<.001
Race				.01
Black	172 (3)	122 (3)	50 (4)	
Hispanic	132 (2)	110 (3)	22 (2)	
Other	50 (1)	45 (1)	5 (0.4)	
White	5165 (94)	4031 (94)	1134 (94)	
Age at biopsy, y				.02
55–60	38 (1)	23 (1)	15 (1)	
60–64	1143 (21)	887 (21)	256 (21)	
65–69	1740 (32)	1385 (32)	355 (29)	
≥70	2598 (47)	2013 (47)	585 (48)	
No. of prior negative biopsies				.5
0	4783 (87)	3732 (87)	1051 (87)	
1	614 (11)	480 (11)	134 (11)	
2	96 (2)	79 (2)	17 (1)	
3	23 (0.4)	15 (0.3)	8 (0.7)	
4	3 (0.1)	2 (<0.1)	1 (0.1)	
No. of previous PSA screens				<.001
2	116 (2)	66 (2)	50 (4)	
3–4	208 (4)	99 (2)	109 (9)	
5–7	2505 (45)	1894 (44)	611 (50)	
≥8	2690 (49)	2249 (52)	441 (36)	
Trial year of biopsy				<.001
1	103 (2)	60 (1)	43 (4)	
2	110 (2)	45 (1)	65 (5)	
3	85 (2)	37 (1)	48 (4)	
4	106 (2)	42 (1)	64 (5)	
5	115 (2)	33 (1)	82 (7)	
6	156 (3)	72 (2)	84 (7)	
7	4844 (88)	4019 (93)	825 (68)	

* Differences between the groups were assessed by χ^2. All statistical tests were two-sided. PSA = prostate-specific antigen.

Table 2. Characteristics of biopsies*

Characteristic	All (N = 5519), No. (%)	Biopsy negative (N = 4308), No. (%)	Biopsy positive (N = 1211), No. (%)	P
PSA at biopsy, ng/mL				<.001
<1	1716 (31)	1546 (36)	170 (14)	
1 to <2	1786 (32)	1434 (33)	352 (29)	
2 to <3	876 (16)	639 (15)	237 (20)	
3 to <4	482 (9)	343 (8)	139 (11)	
4 to <5	352 (6)	185 (4)	167 (14)	
≥5	307 (6)	161 (4)	146 (12)	
PSAV				<.001
Decreasing	1368 (25)	1210 (28)	158 (13)	
0 to <0.05 ng mL^{-1} y^{-1}	1511 (27)	1293 (30)	218 (18)	
0.05 to <0.10 ng mL^{-1} y^{-1}	865 (16)	681 (16)	184 (15)	
0.10 to <0.20 ng mL^{-1} y^{-1}	807 (15)	586 (14)	221 (18)	
≥0.20 ng mL^{-1} y^{-1}	968 (18)	538 (12)	430 (36)	
Positive DRE at biopsy	551 (10)	343 (8)	208 (17)	<.001
Biopsy Gleason score				—
6 or less	—	—	945 (65)	
7	—	—	198 (16)	
8 or more	—	—	58 (5)	
Missing	—	—	10 (1)	
Epstein criteria†	—	—		—
Clinically significant	—	—	651 (54)	
Not clinically significant	—	—	229 (19)	
Missing	—	—	331 (27)	

* Differences between the groups were assessed by χ^2. All statistical tests were two-sided. PSA = prostate-specific antigen; PSAV = prostate-specific antigen velocity; DRE = digital rectal exam.

† Epstein et al. (16). Clinically significant cancer is defined as stage greater than T1c or PSA density of at least 0.15 ng mL^{-1} g^{-1} or Gleason score of at least 7 or tumor in 3 or more cores, or at least one core with more than 50% cancer involvement.

There was little evidence that PSA velocity adds an important level of predictive accuracy to either standard predictors or to PSA alone (Table 4). Using linear regression on all log PSA values to calculate PSA velocity (other definitions of PSA led to smaller increments in AUC), the AUC for prediction of any cancer using the multivariable model increased by 0.007, from 0.702 to 0.709, when PSA velocity was added to the model. AUC increased by 0.010, from 0.682 to 0.692, comparing PSA alone to PSA plus PSA velocity (Table 4). The value of velocity was less for predicting clinically significant or high-grade cancers with increases in AUC of 0.005 and 0.001, respectively, compared with the standard predictors alone (Table 4).

When we investigated the guidelines on PSA velocity explicitly, we did see that PSA velocity predicted cancer in men without a conventional indication for biopsy, that is, men with low PSA and a normal DRE (Table 5). For example, the risk of cancer in men with a PSA velocity above 0.35 ng mL^{-1} y^{-1} is higher than in men with PSA velocity less than this cut point (21% vs 15%) (Table 5). However, superior risk stratification can be achieved simply by choosing a different PSA cut point, especially for the endpoints of high-grade cancer or clinically significant cancer. Following the NCCN guidelines and biopsying men with normal DRE and PSA less than 4 ng/mL if they had a PSA velocity above 0.35 ng mL^{-1} y^{-1} would lead to 115 additional cancers being identified but 433 unnecessary biopsies; a 2.5 ng/mL PSA threshold would result in a very similar number of unnecessary biopsies (n = 436) but would find 24 more cancers. In other words, the PSA threshold of 2.5 ng/mL has the same specificity as the PSA velocity threshold

Table 3. Prostate-specific antigen (PSA) velocity definitions*

PSA velocity measure	No. of subjects analyzed	OR† (95% CI)	P
Linear regression on all log(PSA) values	5519	5.24 (2.52 to 10.9)	<.001
Linear regression on all log(PSA) values 1 y before	1742	0.74 (0.56 to 0.99)	0.037
Linear regression on all log(PSA) values 2 y before	5418	0.83 (0.68 to 1.02)	0.078
Linear regression on all log(PSA) values 3 y before	5519	1.17 (0.81 to 1.69)	0.4
Slope of exactly 2 log(PSA) values within 3 y	5519	3.35 (0.47 to 23.8)	0.2
Linear regression on ≥3 log(PSA) values within 18 mo	130	1.02 (0.31 to 3.35)	1
"Annualized" velocity‡	5234	0.98 (0.95 to 1.00)	0.047

* *P* values obtained from a Wald test on PSA velocity in a univariate logistic regression. All statistical tests were two-sided. CI = confidence interval; OR = odds ratio.

† The odds ratios are for PSA velocity when added to a model including age, log PSA, digital rectal exam, prior biopsy, and family history.

‡ Annualized velocity is calculated by taking three consecutive PSA values (PSA1, PSA2, PSA3) and calculating the mean of the change between each, that is, ([PSA3 − PSA2] + [PSA2 − PSA1])/2.

Table 4. Predictive accuracy of models with and without prostate-specific antigen velocity (PSAV)*

End point	No. of subjects	Area under the curve: Model† without PSAV	Model† with PSAV	log(PSA) only	log(PSA) and log(PSA) velocity
Cancer on biopsy	5519	0.702	0.709	0.682	0.692
Clinically significant cancer‡	5188	0.767	0.772	0.734	0.746
Gleason score 7–10	5509	0.791	0.792	0.780	0.784

* Predictive accuracy defined as area under the curve. PSA = prostate-specific antigen.

† Model consisted of log PSA, family history, DRE, and prior biopsy.

‡ Clinically significant cancer is defined as stage greater than T1c or PSA density of at least 0.15 ng mL^{-1} g^{-1} or Gleason score of at least 7, or tumor in 3 or more cores, or at least one core with more than 50% cancer involvement.

0.35 ng mL^{-1} y^{-1} (87%) but a higher sensitivity (23% vs 19% for any cancer, 41% vs 25% for high-grade tumors, 32% vs 22% for clinically significant disease). Of particular note, use of PSA velocity criterion as per NCCN guidelines would lead to a large number of biopsies, with biopsy recommended in one in seven men without a conventional biopsy indication. Only a small fraction of men with very low PSA, 2.5 ng/mL or less, had a high PSA velocity, and there was no difference in risk of cancer in men above and below PSA velocity thresholds (Table 5).

These negative findings prompted us to conduct additional unplanned analyses. Our aim was to see whether methods of formulating changes in PSA in terms other than PSA velocity might have some clinical role in aiding decisions about prostate biopsy. We first examined a more recently published algorithm of PSA velocity, the risk count method (17), which involves determining the number of times that PSA velocity increases above a certain threshold during the course of a patient's PSA history. Although there was some suggestion that patients who experienced several large rises in PSA had a lower chance of prostate cancer, most results failed to reach statistical significance after adjustment for PSA (Table 6). We also explored whether the percentage change in PSA might be of benefit. Results here were more promising. After adjusting for standard clinical predictors, men who had more than 50% increase in PSA in the year before biopsy, such as from 3 to 4.6 ng/mL, had a reduced risk of a positive biopsy (odds ratio = 0.53; 95% confidence interval = 0.34 to 0.84; $P = .01$). However, very few men met this criterion (170, 3%), limiting its clinical value.

Discussion

We have analyzed perhaps the only dataset available that can evaluate the guidelines concerning PSA velocity. We found no evidence to support prostate biopsy in men with high PSA velocity in the absence of other indications, such as a positive DRE or high PSA. Overall, PSA velocity did not importantly add predictive accuracy to a standard predictive model or to just PSA alone and, more specifically, PSA velocity cut points had inferior risk separation compared with PSA cut points in men with low PSA and negative DRE. In other words, if a clinician feels that the current PSA thresholds are insufficiently sensitive, he or she would be better off identifying patients to biopsy by using low PSA thresholds than by adding PSA velocity as a criterion for biopsy.

Our findings appear to contradict a body of evidence apparently supporting the relationship between PSA velocity and prostate cancer, but this contradiction is more apparent than real. First, like other authors, we found strong evidence for a univariate association between PSA velocity and positive biopsy ($P < .001$). In general, this lead to higher risks of cancer above specific PSA velocity cut points than below. However, we also found that PSA velocity does not add important predictive value to PSA and other standard predictors; in other words, we did not find that the use of a PSA velocity criterion for biopsy would improve clinical decision making. To our knowledge, these questions have not been addressed by prior authors (18). That PSA velocity is strongly associated with biopsy outcome on univariate, but not multivariable, analysis, is easily explained by collinearity. The correlation between PSA and PSA velocity was close to 0.9 when analyzing all PSA values before biopsy, and it is naturally difficult for a marker to add value to a predictor with which it has a strong correlation.

Our findings are consistent with several other studies. Investigators from the Rotterdam center of the European Randomized trial of Screening for Prostate Cancer (ERSPC) have reported that PSA velocity does not help predict biopsy outcome (19) or clinically significant prostate cancer (20). Eggener et al. (21) used a more sophisticated modeling approach to find a very small increment in predictive accuracy associated with PSA velocity, largely as a result of a small number of men with very high PSA velocities and a reduced risk of cancer. This negative association was likely attributable to high PSA velocity being associated with benign inflammatory conditions (21). Eggener's result was replicated almost exactly by our own recent study (22) of two ERSPC cohorts, in which we similarly found a very small increment in predictive accuracy associated with PSA velocity, again explained largely by a minority of men with reduced risk at high PSA velocities (22). Together with these prior reports, our findings suggest that men with a sudden large rise in PSA should be carefully evaluated for benign disease, possibly including a repeat PSA, before referral for prostate biopsy.

One possible argument against our conclusions might be that, although PSA velocity does not help find prostate cancer, it does help detect the aggressive cancers most likely to shorten a man's life; that is, PSA velocity is of value for prognostication if not detection. Supporters of this argument might point to Carter's findings (10) that a PSA velocity of 0.35 ng mL^{-1} y^{-1} is associated with aggressive cancers diagnosed many years later (10), or D'Amico's oft-cited finding (23) that a PSA velocity of 2.0 ng at the time of definitive treatment is a predictor of cancer-specific death (23). Yet, we found no evidence that PSA velocity helps to detect more aggressive cancers. Indeed, the small increment in predictive

Table 5. Distribution of prostate-specific antigen (PSA) and prostate-specific antigen velocity (PSAV) cut points for men without other indications for biopsy with corresponding rates of cancer, high-grade cancer, and clinically significant cancer*

PSA and PSAV cut points	All subjects, No. (%)		All cancers, No. (%)		High-grade cancers, No. (%)		Clinically significant cancers, No. (%)	
	Below cut point	Above cut point	Patients below cut point	Patients above cut point	Patients below cut point	Patients above cut point	Patients below cut point†	Patients above cut point†
PSA < 4 ng/mL, negative DRE								
PSAV, ng mL^{-1} y^{-1}								
0.35	3319 (86)	548 (14)	488 (15)	115 (21)	71 (2)	24 (4)	214/3199 (7)	62/521 (12)
0.5	3523 (91)	344 (9)	538 (15)	65 (19)	78 (2)	17 (5)	240/3394 (7)	36/326 (11)
0.75	3720 (96)	147 (4)	575 (15)	28 (19)	88 (2)	7 (5)	259/3578 (7)	17/142 (12)
PSA, ng/mL								
2	2936 (75)	985 (25)	382 (13)	232 (24)	44 (1)	51 (5)	151/2836 (5)	130/934 (14)
2.5	3346 (85)	575 (15)	475 (14)	139 (24)	56 (2)	39 (7)	192/3220 (6)	89/550 (16)
PSA < 2.5 ng/mL, negative DRE								
PSAV, ng mL^{-1} y^{-1}								
0.35	2970 (92)	266 (8)	408 (14)	49 (18)	50 (2)	4 (2)	169/2865 (6)	16/252 (6)
0.5	3098 (96)	138 (4)	438 (14)	19 (14)	51 (2)	3 (2)	179/2986 (6)	6/131 (5)
0.75	3193 (99)	43 (1)	448 (14)	9 (21)	52 (2)	2 (5)	182/3076 (6)	3/41 (7)

* DRE = digital rectal exam. High-grade is Gleason 7 or greater; clinically significant cancer is defined as stage greater than T1c or PSA density of at least 0.15 ng mL^{-1} g^{-1} or Gleason score of at least 7, or tumor in 3 or more cores, or at least one core with more than 50% cancer involvement.

† As data are missing for some men, the denominator is listed for this analysis.

accuracy associated with PSA velocity was reduced when we restricted our analyses to high-grade cancers or those that met the Epstein definition of clinical significance.

Moreover, doubts can be raised about whether PSA velocity is indeed of value for prognostication. Carter (10) and D'Amico's (23) articles were based on a small number of events (20 and 27, respectively) and neither examined whether PSA velocity was of incremental benefit, for example, by comparing AUC with and without PSA velocity. Indeed, in a systematic review of the literature (18), we found a near complete absence of evidence that PSA velocity adds predictive value to PSA. Our own group has evaluated all 22 definitions of PSA velocity and PSA doubling time on a radical prostatectomy dataset (24). We found that most definitions did not add predictive accuracy to PSA alone for the end point of either recurrence or metastasis; a small number of definitions added a small amount to the AUC, although not importantly more than would be expected by chance. Furthermore, no definition added to the prediction of both recurrence and metastasis, and the previously cited "red flag" of 2 ng mL^{-1} y^{-1} did not help predict either outcome.

This work has several potential limitations. First, it is possible that there might be better schedules to measure PSA and better methods to calculate PSA velocity. Yet, patients in the PCPT were scheduled by protocol to have yearly PSA testing, in line with typical guidelines on PSA screening, including those of the NCCN. Moreover, we analyzed our findings using a large number of different approaches to the calculation of PSA velocity and did not find important differences in our results. Second, we have previously been criticized as inappropriately focusing on accuracy rather than reclassification (25). We believe that both are important when evaluating a marker. It is hard to see how a marker can lead to important reclassification if it does not materially add to prediction and therefore report both in this study. Most pertinently, our study is a direct evaluation of a published guideline, and the appropriate methods are self-evident. Third, it might also be suggested that the cancers detected in PCPT were "clinically irrelevant" because of the inclusion of the end-of-study biopsy for men with low PSAs. Yet, our results were similar when analyses were restricted to high-grade cancers or to clinically significant cancers; furthermore, our study methods are able to replicate exactly those recommended in the NCCN and AUA guidelines, biopsy for men with low PSA but high PSA velocity.

It is impossible to prove a negative and it is not inconceivable that PSA velocity could have a role in prostate cancer detection. For example, the men in our study with low PSA and negative DRE were screened for 7 years; therefore, conceivably, PSA velocity could be of value for men with either greater or fewer years of screening. Similarly, although we found no evidence that PSA velocity differentially detected aggressive cancers, our cohort has not been followed until death, and it is conceivable that some differences may emerge on very long-term follow-up. That said, guidelines should generally be based on the presence of positive evidence, not on the absence of negative evidence. It is difficult to support the inclusion of PSA velocity in a guideline on the grounds that it might conceivably be shown to be of benefit in some future study.

Table 6. Exploratory analysis of risk count method for calculating prostate-specific antigen velocity(PSAV) *

Risk count definition	Univariate, OR (95% CI)	*P*	Adjusted for log(PSA), OR (95% CI)	*P*
Indicator for whether PSA rise > 0.2 ng mL^{-1} y^{-1} at least once	1.96 (1.49 to 2.58)	<.001	0.95 (0.69 to 1.31)	>.20
No. of times PSA rise > 0.2 ng mL^{-1} y^{-1}	1.28 (1.19 to 1.36)	<.001	0.99 (0.90 to 1.09)	>.20
Indicator for whether PSA rise > 0.4 ng mL^{-1} y^{-1} at least once	1.50 (1.25 to 1.79)	<.001	0.81 (0.65 to 1.01)	.061
No. of times PSA rise > 0.4 ng mL^{-1} y^{-1}	1.16 (1.07 to 1.26)	<.001	0.81 (0.73 to 0.90)	<.001

* The association between risk count and outcome was assessed by logistic regression. All statistical tests were two-sided. CI = confidence interval; OR = odds ratio.

In conclusion, we have formally evaluated published guidelines on PSA velocity for prostate cancer detection, examining several definitions of cancer and numerous different methods of calculating PSA velocity. We found no reason to believe that implementation of the guideline would improve patient outcomes; indeed, its use would lead to a large number of unnecessary biopsies. We therefore recommend that organizations issuing policy statements related to PSA and prostate cancer detection remove references to PSA velocity.

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Funding

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Notes

Dr. Hans Lilja holds a patent for free PSA assays.

The funders did not have any involvement in the design of the study; the collection, analysis, and interpretation of the data; the writing of the manuscript; or the decision to submit the manuscript for publication. The initial analyses were designed by A. J. Vickers and H. Lilja in New York and implemented by C. Till and C. M. Tangen in Seattle. I. M. Thompson, who also had access to the data, advised on the interpretation of the results and suggested additional analyses. All authors were involved in the writing and revision of the manuscript.

Affiliations of authors: Departments of Epidemiology and Biostatistics (AJV) and Clinical Chemistry (HL), Memorial Sloan-Kettering Cancer Center, New York, NY; Cancer Prevention Program, Fred Hutchinson Cancer Research Center, Seattle, WA (CT, CMT); University of Texas Health Science Center at San Antonio (IMT).

Richard Stuart Pelman, M.D.

Record Review:	$375.00/hour
Deposition/Court Testimony:	$2,500.00/day

July 29, 2019

Matt Waldrop
Assistant United States Attorney
U. S. Department of Justice
700 Stewart Street, Suite 5220
Seattle WA, 98101-1271

Re: Farvour v. United States of America, No. 18-5386-BHS

Mr. Waldrop,

I am Board Certified in Family Medicine with 32 years of Primary Care practice experience. I attended the University of Colorado at Boulder for my undergraduate education and received my Medical Degree from the University of Colorado. My Internship was completed at the University of Colorado Family Medicine program and the remainder of my Family Medicine Residency was completed at Swedish Hospital in Seattle. I am licensed to practice medicine in the State of Washington since 1996, having previously practiced medicine in Alaska (Public Health Service) and Colorado.

In preparing my opinions in this case I have reviewed the Complaint from Plaintiffs Robert Farvour and Elaine Farvour, as well as medical records from Peace Health, VA Portland Health Care System, declarations from Michael Brawer MD and Peter McGough MD, the VA PSA Test For Prostate Cancer Screening pamphlet, as well as depositions from Robert and Elaine Farvour, Jesse Talalotu MD, Tracy Gutman MD, Eileen Horner MD, and Anjali Ohri MD.

To review briefly, Robert Farvour, who received his primary care through the Vancouver Division of the Veterans Administration Portland Health Care System, was diagnosed in February of 2017 with metastatic prostatic adenocarcinoma after presenting to urology for urinary retention. Following surgery for his urination retention, Mr. Farvour was noted to have a PSA of 289. It is noted that Mr. Farvour,

through his routine annual medical visits, had PSA screening between 2006 and 2011 but not after 2011, with the results as follows:

4/10/2006	1.6
5/25/2007	1.5
9/16/2008	2.3
9/23/2009	2.6
10/12/2011	2.9

The Complaint alleges that the failure to "follow-up and perform PSA testing" constitutes medical negligence and that the Vancouver Division of VA Portland Health Care System and its employees breached its duty to provide informed consent by not informing the Plaintiffs of risks and alternatives (presumably regarding PSA screening for prostate cancer).

I have been asked to provide my medical opinion regarding the standard of care for primary care physicians regarding prostate cancer screening during the period of time between 2012 and 2017.

I have also been asked to provide guidance regarding what Mr. Farvour's life expectancy would have been in the absence of prostate cancer given his previous medical history.

All of my opinions are provided on a more probable than not basis or to a reasonable degree of medical certainty and I reserve the right to supplement or amend my opinions should more information become available to me.

It is my opinion that the primary care provided through the VA for Mr. Farvour between 2012 and 2017 was within the standard of care with regard to prostate cancer screening. Jesse Talalotu MD, Tracy Gutman MD, Eileen Horner MD and Anjali Ohri MD have indicated in their depositions that they follow the U.S Preventive Services Task Force (USPSTF) screening recommendations.

The USPSTF describes itself as "an independent panel of nonfederal experts in prevention and evidence-based medicine. The Task Force carefully assesses the evidence and makes recommendations

about preventive services such as screening tests, counseling services, or preventive medications that are provided in clinic settings, and are intended to prevent disease or improve health outcomes from heart disease, cancer, infectious diseases, and other conditions and events that affect the health of children, adolescents, adults, older adults, and pregnant women."

It is very important to note that during the time period in question there was not one standard of care for prostate cancer screening. Prostate cancer screening has been a controversial area. Other professional organizations have their own prostate cancer screening recommendations that are not all the same, including the American Urological Association, the American Cancer Society, the American College of Preventive Medicine, among others. From a primary care perspective, the USPSTF is considered the gold standard for evidence-based screening guidelines.

The USPSTF revised their prostate cancer screening recommendation in 2012 as follows:

"The USPSTF recommends against PSA-based screening for prostate cancer (grade D recommendation). Do not use prostate-specific antigen (PSA)-based screening for prostate cancer. The benefits of PSA based screening for prostate cancer do not outweigh the harms. "

A grade D recommendation indicates that "the USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. Suggestions for practice: Discourage the use of this service."

Another potential prostate cancer screening test is digital rectal examination (DRE). According to the USPSTF "screening tests or programs that do not incorporate PSA testing, including digital rectal examination alone, have not been adequately evaluated in controlled studies." No recommendation is made regarding DRE and another source of screening guidelines, UpToDate, that was also mentioned in the physician depositions, recommends against DRE for prostate cancer screening.

Regarding the question of informed consent, the USPSTF recommends that "physicians should not offer or order PSA screening unless they are prepared to engage in shared decision making that enables an informed choice by patients." If not ordering PSA screening there is no recommendation to engage in shared decision making.

Mr. Farvour is a Vietnam Veteran and was exposed to Agent Orange in the war. Exposure to Agent Orange is considered to be a risk factor for prostate cancer. The USPSTF notes that "few data exist on the outcomes or effect of PSA testing and treatment in these persons" and does not make any different recommendations regarding PSA screening in these individuals.

Regarding the question of life expectancy, a starting point is the actuarial additional life expectancy of a 66 year old male (Mr. Farvour's age at prostate cancer diagnosis). The United States Life Tables, 2017, from the National Vital Statistics Report notes that a white male between the ages of 66 and 67 has an additional 17.2 years of life expectancy.

Mr. Farvour, prior to his diagnosis of prostate cancer, is noted to have the following medical history:

Alcohol abuse (variously reported as 3-4 or 5-6 per day)
History of knee surgery
Elevated liver enzymes
Insomnia
Ulcerative colitis
History of tobacco use (40 pack/years)
HTN
Hypercholesterolemia
PTSD

While many of the above diagnoses could impact an individual's life span if poorly controlled, the 2 diagnoses that absolutely are known to shorten life are smoking and excessive alcohol consumption.

Unfortunately, I am unable to find any actuarial tables regarding years of life lost in the setting of smoking and excessive alcohol use.

There are a number of studies however that do try to quantify the magnitude of years of life lost for individuals who smoke and use alcohol excessively.

Probably the most useful study regarding alcohol use is in the Lancet from 2018 which noted a decreased life expectancy for alcohol use above 350 g/week of 4-5 years. (In the United States, one "standard" drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in: 12 ounces of regular beer, which is usually about 5% alcohol. 5 ounces of wine, which is typically about 12% alcohol. Therefore, 350 g is the equivalent of 25 drinks a week or 3.6 per day).

As for smoking, according to the Centers for Disease Control (CDC), "Life expectancy for smokers is at least 10 years shorter than for nonsmokers."

Based on the above, it is reasonable to assume that Mr. Farvour's life expectancy, regardless of his prostate cancer diagnosis, would have been less than the standard by between 10 and 15 years.

In summary, during the time period in question, there was not one standard of care for prostate cancer screening. Jesse Talalotu MD, Tracy Gutman MD, Eileen Horner MD, and Anjali Ohri MD all mention the USPSTF when discussing not ordering PSA testing for prostate cancer screening. USPSTF is very highly respected and considered from a primary care perspective to be the gold standard for evidence-based screening guidelines. The choice to follow the USPSTF guideline and the decision not to use PSA screening is well within the standard of care. Likewise, very reputable sources of medical practice guidelines such as UpToDate recommend against DRE for prostate cancer screening. Since no prostate cancer screening was being performed, there was no recommendation to have a shared decision conversation. And finally, according to the USPSTF, evidence is not sufficient to suggest any different screening recommendations for patients with a history of exposure to Agent Orange.

Sincerely,

/s/ Kelly R. White, M.D.

Kelly R. White, M.D.

CURRICULUM VITAE

KELLY ROSS WHITE MD
[redacted]
SEATTLE, WASHINGTON 98199
Home [redacted]
Cell [redacted]

Education and Work

10/13 – Present The Vasectomy Clinic
Vasectomy Surgeon

11/15 – Present Edmonds Family Medicine
Urgent Care

7/06 – 12/14 The Polyclinic, Downtown Clinic
Family Medicine without Obstetrics
Hospital privileges, active: Swedish Medical Center

Other positions held at The Polyclinic:
Board of Directors 2013 - 2014
Finance and Operations committee Chair 2010-1012
Finance and Operations Committee Member 2007-2009

12/05 - 7/06 Pacific Medical Centers, Lynwood Clinic
Family Medicine without Obstetrics
Hospital privileges: Swedish Medical Center

1/02 - 12/05: Medical Director, Pacific Medical Centers, 1101 Madison:
A 0.8 FTE administrative position directing all medical and surgical subspecialties including a Hospitalist program and a primary care Internal Medicine clinic.
Family Medicine without Obstetrics (0.2 FTE)

2/98 – 1/02: Pacific Medical Centers, Northgate Clinic
Family Medicine without obstetrics
Hospital privileges: Swedish Medical Center and Northwest Hospital

Additional positions held with Pacific Medical Centers:
Pacific Medical Centers' representative member of Virginia Mason Hospital Medical Staff Committee, 2/03 – 12/05.
Patient Care Committee Chair: A 0.1 FTE administrative position focused on clinical quality and utilization management, 2/99 – 1/02.
Compensation and Benefits Committee Chair: An appointed position

responsible for development and review of clinical provider compensation and benefits, 1/2000 – 6/03.

Compensation and Benefits Committee member, 99 – 12/2000.

Provider Forum (formerly Medical Staff Executive Committee): Member of a committee (elected by the Medical Staff) with the purpose of advising the CMO in matters pertaining to the medical staff, 6/99 – 6/01.

Interim Northgate Clinic Medical Director: 5/01 – 9/01.

Washington Diabetes Collaborative: Site coordinator for the pilot implementation at PacMed's Northgate clinic, 3/01 – 1/02.

Premera Blue Cross Medical Quality Committee member, 3/00 – 1/02.

8/96 – 1/98: Everett Family Practice Center
Full spectrum Family Medicine including Obstetrics
Hospital privileges: Providence General Hospital, Everett, WA

6/94 – 6/96: Swedish Family Medicine Residency, R2 and R3 years
Swedish Hospital, Seattle, WA

8/89 – 4/94: Public Health Service/Indian Health Service
Southeast Alaska Regional Health Corporation
Full spectrum Family Medicine including Obstetrics
Hospital Privileges: Bartlett Memorial Hospital, Juneau, AK

1988 – 89: Family Care Medical Center
Outpatient General Practice
Hospital Privileges: Rose Hospital, Denver, CO

1988 – 89: Rose Hospital Community Clinics
Outpatient General Practice
Denver, CO

6/87 – 6/88: University of Colorado Family Medicine Residency, Internship
University Hospital, Denver, CO

8/83 – 5/87: University of Colorado Health Sciences Center
Degree: MD with Honors, 5/23/87

8/79 – 5/83: University of Colorado
Major: Biochemistry

2/81 – 6/81: University of Costa Rica, Central America, semester abroad

Additional Postgraduate Medical Training and Certification

7/03 and 4/13 Family Medicine Board Recertification, expires 2023

7/96: Family Medicine Board Certification

11/89 – 12/89: High risk obstetrics, Gallup Indian Medical Center

Awards/Honors

AAFP Mead Johnson Award for Excellence in Family Medicine, 1995

Public Health Association Achievement Medal, 1992

Alpha Omega Alpha and Phi Beta Kappa

Volunteer Activities

1993 – 1994: Partners in Action for Teen Health: Founding member of community coalition advocacy group for teen health care.

1992 – 93: Juneau School Board Health Care Committee: Physician advisor for the establishment of a high school based health care clinic.

1978 – 83: National Ski Patrol volunteer, Keystone ski area, CO.

Professional Interests/Additional Skills

Preventive medicine, public health and cross-cultural health care.
Vasectomies (No scalpel/No needle) and other minor surgical procedures.

Personal Interests

Family: Wife Katy, daughter Anna (18), and son Noah (16).
Cycling, skiing, sailing, lutherie and fine woodworking.

Languages

Spanish: fluent, spoken and written

Kelly R White, M.D.
2846 44th Ave. W.
Seattle, WA 98199
206-972-6655
kellyrwhite@comcast.net

Fee Schedule for Medical Legal Consulting

Records review, Consultation, and Reports	$ 500 per hour
Depositions	$2,400 for up to 4 hours $500 for each additional hour
Trial Testimony	$4,000 per half-day

West
ECONOMICS, INC.
Forensic Economics
Litigation Consulting &
Testifying Economic Experts

Curriculum Vitae
Erick C. West, M.A.

OCCUPATION:	President; West Economics, Inc.
AREAS OF SPECIALIZATION:	Business valuation and appraisal services, forensic economics and quantification of commercial and personal economic loss
EXPERT WITNESS:	Washington, Idaho & Oregon (Judge and Jury Trials)
EDUCATION:	Master of Arts, Economics Washington State University – 2000 Bachelor of Arts, Economics Washington State University – 1998
PROFESSIONAL ASSOCIATIONS:	American Society of Appraisers (Business Valuation) National Association of Forensic Economics American Academy of Economic and Financial Experts

WORK EXPERIENCE:

2013 – Present	West Economics, Inc., President
2003 – 2012	Harper Incorporated, Senior Economist
2001 – 2002	Estate of S.R.D., Trainer/Job Coach
2000 – 2001	Merrill Lynch, Financial Advisor

PROFESSIONAL EDUCATION & TRAINING

"Annual Meeting," American Academy of Economic and Financial Experts (AAEFE), Las Vegas, NV, April 2010.

"National Business Valuation Conference," American Society of Appraisers, Las Vegas, NV, November 2008.

"SE100: National Uniform Standards of Professional Appraisal Practice (USPAP)," and successful completion of the ASA exam, American Society of Appraisers, Las Vegas, NV, June 2007.

"BV204: Business Valuation Case Study," and successful completion of the ASA exam, American Society of Appraisers, Los Angeles, CA, May 2006.

10220 N. Nevada Street, Suite 110
Spokane, Washington 99218
email: ewest@econexpert.com
website: www.econexpert.com
509.747.5850, Fax 509.747.5859

"BV203: The Market Approach," and successful completion of the ASA exam, American Society of Appraisers, Los Angeles, CA, February 2006.

"BV202: The Income Approach," and successful completion of the ASA exam, American Society of Appraisers, Manhattan Beach, CA, October 2005.

"BV201: Introduction to Business Valuation," and successful completion of the ASA exam, American Society of Appraisers, Manhattan Beach, CA, July 2005.

"2005 Annual Spring Conference," American Rehabilitation Economics Association (AREA), Reno, NV, May 2005.

SPEAKING ENGAGEMENTS

"How to Use Expert Testimony More Effectively in Proving Economic Damages in Personal Injury Cases," 2015 Idaho Trial Lawyers Association Fall Seminar, McCall, ID, Oct 2015.

VALUATION AND LITIGATION EXPERIENCE

Valuation and economic loss analysis of businesses and individuals including physicians, dentists, attorneys, engineers, optometrists, dermatologists, chiropractors, physical therapists, massage therapists, auto dealerships, stock brokers, veterinarians, logging companies, construction companies, real estate agents, auto and aircraft mechanics, River Park Square, movie theaters, rehabilitation counselors, teachers, pharmaceutical sales reps, welders, electricians, insurance sales, plumbers, military personnel, long-haul truckers, IT specialists, CAD drafters, firemen, police officers, accountants, steelworkers, bank managers, telemarketers, janitors, assemblers, cooks, dietitians, card dealers, farmers and airline employees and many others.

Determination of damages in civil cases involving personal injury, wrongful death, employee discrimination, class actions, legal/accounting malpractice, breach of contract, partnership disputes and business interruption claims.

Business valuations for divorce, business purchases, stock sales, partnership disputes and business loan approval.

Other litigation experience including the present value calculation of Life Care Plans (future medical costs) and valuation of employee pension plans including state, federal, military and union covered employees.

West
ECONOMICS, INC.
Forensic Economics
Litigation Consulting &
Testifying Economic Experts

2019 Fee Schedule

Hourly Rates

Erick C. West, Principal, M.A.	$ 300
Trial and Deposition Testimony[1]	$ 300
(1.5 hour minimum charge for depositions)	
Travel Time *(no charge in Spokane/Kootenai County)*[2]	$ 135
Clerical	$ 75

[1] *Prepayment is required for depositions scheduled outside of Spokane/Kootenai County. An estimate of all fees will be provided, which is due at least 3 business days prior to the deposition.*

[2] *All out-of-pocket expenses (i.e. airfare, hotel, car rental, fuel, etc.) are billed at cost.*

10220 N. Nevada Street, Suite 110
Spokane, Washington 99218
email: ewest@econexpert.com
website: www.econexpert.com
509.747.5850, Fax 509.747.5859

Dana Penilton Consulting, Inc.

6312 SW Capitol Hwy.
#418
Portland, OR 97239-1937

office 503-701-9009
fax 1-855-839-0956
danapen@comcast.net

www.danapenilton.com

Preliminary Life Care Plan
for
Robert Farvour

Prepared by:
Dana Penilton, RN, BSN, CCM, CLCP
Certified Life Care Planner

Dana Penilton Consulting, Inc.
6312 SW Capitol Hwy #418
Portland, OR 97239-1937
Phone: (503) 701-9009
Fax: 1-855-839-0956
danapen@comcast.com
www.danapenilton

Confidential Document-For Professional Use Only

Life Care Plan Evaluee: Robert Delano Farvour
Date of Birth: September 18, 1950
Date of Diagnosis: February 16, 2017
Date of Report: July 29, 2019

Preliminary Life Care Plan Assessment and Opinions

Prepared by Dana Penilton RN, BSN, CCM, CLCP

Mr. Farvour's Life Care Plan is being completed at the request of Whitney Passmore, Esq. A Life Care Plan is intended to be a dynamic document and this plan is intended to be revised and updated to reflect Mr. Farvour's medical condition changes, medical complications, response to treatment and the clinical impact of his medical condition upon his health and well-being. Life Care Planning is a comprehensive, multi-disciplinary approach[1,2] which systematically documents the needs of a person after a catastrophic event in addition to projecting costs for needed goods and services over an estimated life-span. The objective of Life Care Planning is to maximize a person's independence, functional abilities, community access, mental well-being and quality of life as well as promote vocational and/or leisure and productive activities[3,4,5] within the parameters of an injury/illness. Mr. Farvour expressed that his goal to spend time with his daughters and grandchildren. Life Care Plan recommendations are based on careful consideration of Mr. Farvour's clinical status, are indicated on a more likely than not basis, have been determined to be medically necessary based on medical evidence with the understanding that the interventions will be implemented to mitigate health complications, lifetime needs and associated costs by provision of appropriate goods, services and support at the appropriate time.

The purpose of Life Care Planning is to assist the evaluee with achieving optimal outcomes (such as maximizing independence, functional abilities, community access and mental well-being), prevent and/or reduce complications (and associated medical treatment),[6] as well as promote vocational and/or productive activities and leisure pursuits[7] with the overall goal to improve quality

[1] Pennachio F., Merritt J.L. (2014, September). Working Together Physiatrist & Life Care Planner in Developing a Comprehensive LCP. *International Symposium on Life Care Planning.* Lecture conducted from Minneapolis, Minnesota.
[2] Masterson J., Woodard L., Mitchell N., Penilton D., Smolarski R., Mertes A., Marcinko D., Thomas K., Turner D. (2019). International Academy of Life Care Planners' position paper on transdisciplinary practice. *Journal of Life Care Planning.* 17 (2): 3-4.
[3] International Association of Rehabilitation Professionals (IARP) and International Academy of Life care Planners (IALCP), The Life Care Planning Section of the International Association of Rehabilitation Professionals. (2015). Standards of Practice for Life Care Planners.
[4] Johnson, C., Pomaranz J., Stetten N. Consensus and majority statements derived from Life Care Planning Summits held in 2000, 2002, 2004, 2006, 2008, 20109, 2012, 2015 and 2017 and updated via Delphi study in 2018. *Journal of Life Care Planning.* 2018; 16(4): 15-18.
[5] Steward, D., Reid C., Riddick-Grisham, S., Cyphers, G. (2014, September) The Importance of Productive Activity in Life Care Planning. *International Symposium on Life Care Planning.* Lecture conducted from Minneapolis, MN.
[6] International Academy of Life Care Planners (IALCP), The Life Care Planning Section of the International Association of Rehabilitation Professionals (IARP) (2015) *Standards of Practice for Life Care Planners: Third Edition*
[7] Steward, D., Reid C., Riddick-Grisham, S., Cyphers, G. (2014, September) The Importance of Productive Activity in Life Care Planning. *International Symposium on Life Care Planning.* Lecture conducted from Minneapolis, MN.

of life.[8] Additionally the life care plan should serve as a lifelong guide to assist in the delivery of health care services with recommendations supported by medical foundation.[9,10]

Mr. Farvour's life care plan is preliminary to assist Ms. Passmore with mediation scheduled prior to my retention. Mr. Farvour's life care plan is being completed in adherence with Life Care Plan Standards of Practice and Life Care Planning Consensus and Majority Statements (best practices) however, development of his life care plan remains 'in process' therefore this report is preliminary. Review of available medical records was completed although finalization of life care plan cannot be completed until updated documentation is available as the most recent medical report was dated May 4, 2018. Collaboration with medical specialists to be retained by Ms. Passmore is pending and required prior to completing Mr. Farvour's life care plan. Ms. Passmore was informed of my request to complete onsite assessment on 4-10-19; as of the time of the preliminary life care plan this decision remained pending. Review of research, literature and treatment guidelines related to Mr. Farvour's clinical status was initiated; this will be completed when current medical records are available for review and analysis. I reserve the right to amend or supplement this report if additional clinical or medical information becomes available or Mr. Farvour's clinical status changes.

My opinions are based on review of medical records and documentation provided by Ms. Whitmore including:

- USA0 1-801 R.D.Farvour
- LCP prepared by Robert Cooper MD
- Declaration of Michael K. Brawer MD
- Present Value Assessment by William Davenport
- Declaration of Robert Farvour
- Declaration of Peter M. McGaugh, MD
- R.D.Farvourv1
- Dkt1 Complaint
- R.D.Farvour ECG
- 2019-03-18-Plf Resp to USA's ROG & RFP 1st Set w-Supp Answers
- Farvour,__Robert,__OHSU_Hospitals_and_Clinics__Medical__181117068
- Farvour,__Robert,__PeaceHealth_-_St._John_Medical_Medical__181212851
- Farvour,__Robert, __PeaceHealth_Medical_Group_Mic,_Medical_190308066
- Farvour,__Robert,__Longview_Urology,__Billing_and_Medical__18106673
- Farvour, Elaine, Exhibit 1, 7-3-19.pdf
- Farvour, E070319(1).pdf (Elaine Farvour Deposition)

As noted, updated medical records are required to finalize Mr. Farvour's life care plan. Additionally, the following documentation is pending review to allow incorporation into Mr. Farvour's life care plan:

- USAO 4501-4564 R.D.Farvour(2).pdf

[8] Steins S., Fawber H., Yuhas S. The Person with a Spinal Cord Injury: An Evolving Prototype for Life Care Planning. *Physical Medicine and Rehabilitation Clinics of North America*. 2013;24:419-444.

[9] International Academy of Life Care Planners (IALCP), The Life Care Planning Section of the International Association of Rehabilitation Professionals (IARP) (2015) *Standards of Practice for Life Care Planners: Third Edition*

[10] *Johnson, C. Consensus and Majority Statements* Derived from Life Care Planning Summits Held in 200, 2002, 2004, 2006, 2008, 2010, 2012 and 2015. *Journal of Life Care Planning. 2015: 13,4:35-38.*

- Robert Farvour Deposition
- Updated medical records from 5-4-18 to current

Introduction

The purpose of this evaluation is to assess the extent to which deficits and sequela resulting from Mr. Farvour's diagnosis of malignant neoplasm of prostate[11] and secondary malignant neoplasm of bone[12] impact his future medical care and independent living needs. Mr. Farvour has under the care of Choong Kim MD undergone extensive diagnostic studies, radiation oncology, hormonal therapy.[13,14,15,16,17,18] His medical course has been complicated by emergency department and hospital admission,[19,20,21] cervical dysphagia,[22] vocal cord paralysis status post Cymetra injections,[23,24,25,26,27] thrombocytopenia,[28] pain requiring medical management,[29,30,31] and mild orthostasis.[32]

Interview with Mr. and Mrs. Farvour

On April 10, 2019 Ms. Passmore was informed of my request to complete onsite assessment; as of the time of the preliminary life care plan this decision remained pending.

Diagnoses

788.20 Urinary Retention
600.01 Benign Prostatic Hyperplasia (BPH) with Obstruction
J38.01 Unilateral complete paralysis of vocal cord
R49.0 Dysphonia
T17.908S Aspiration into airway, sequela
R13.14 Dysphagia, pharyngoesophageal phase
D69.3 Immune thrombocytopenic purpura
E43 Unspecified severe protein-calorie malnutrition
N17.9 Acute kidney failure
D61-818 Other pancytopenia
C79.51 Secondary malignant neoplasm of bone
C61 Malignant neoplasm of prostate

[11] 2-16-17 PeaceHealth, Pathology, Naquib Osman Laila MD
[12] 3-3-17 Nuclear Medicine, Bone Single-photon emission computed tomography (SPECT), Hasan Osman MD
[13] 3-21-17 PeaceHealth Radiation Oncology Progress Note, Choong Kim MD
[14] 3-30-17 PeaceHealth Radiation Oncology Progress Note, Choong Kim MD
[15] 4-18-17 PeaceHealth, Zafer Yildirim MD
[16] 4-22-17 PeaceHealth, Discharge Summary, Gerardo Melgar MD
[17]4-26-17 PeaceHealth Radiation Oncology Progress Note, Choong Kim MD
[18] 5-4-17 Radiation Oncology Consult, Choong Kim MD
[19] 4-18-17 PeaceHealth Emergency Department, Colin Jackson MD
[20] 6-2-17 Progress Note Michael Bartlett MD
[21] 1-31-18 St. John Emergency Department
[22] 5-3-17 Operative Report, Gordon Matlock MD
[23] 4-27-17 PeaceHealth, Jeffery Davis MD, Otolaryngology
[24] 6-8-17 OHSU Voice Evaluation, Karen Drake MA, CCC
[25] 7-3-17 OHSU Progress Note, Paul Flint MD
[26] 7-27-17 OHSU Paul Flint MD
[27] 8-30-17 OHSU Paul Flint MD
[28] 4-28-17 Michael Bartlett MD
[29] 4-18-17 PeaceHealth, Zafer Yildirim MD
[30] 7-20-17 Radiation Oncology Follow Up Note, Choong Kim MD
[31] 10-11-17 Radiation Oncology Follow Up Note, Choong Kim MD
[32] 3-22-18 Progress Notes, Clifford Schostal MD

Past Medical History

Arthritis
N40.1 Benign prostatic hypertrophy (BPH)
Colon polyp
History of colon polyps
Essential Hypertension
Mobility impaired due to right knee pain/dysfunction
Osteopenia
Pain right knee-constant
Ulcerative colitis (HCC)
LEFT should pain after fall
N13.8 Obstructive and reflux uropathy
R33.8 Retention of urine
E78.5 Hyperlipidemia
Z96.652 Presence of LEFT artificial knee joint
Z87.891 Personal history of nicotine dependence
K51.911 Ulcerative colitis, unspecified with rectal bleeding
Z68.25 Body mass index 25.0-25.9

Significant Procedures and Surgeries

Carpal tunnel release, bilateral
Cataract extraction with intraocular lens implant
Colonoscopy
Eye surgery
Knee arthroscopy RIGHT
Prostate Surgery 2-14-17, TURP (transurethral resection of prostate)
Total knee arthroplasty RIGHT 9-5-13
Revision Total Knee arthroplasty RIGHT 11-22-16 with hardware removal from previous surgery
Rotator cuff repair

Social Information

Mr. Farvour is married to Ms. Elaine Farvour with whom he has two daughters Jennifer and Danielle as well as three grandchildren. Mr. and Ms. Farvour live in a single level home they purchased in Kelso Washington. There is a single step entry to front and garage door[33] and it is understood there are two steps into living room.[34]

Military

Mr. Farvour is a Vietnam veteran and his wife reports he struggles with post-traumatic stress disorder and agent orange exposure.[35]

[33] 7-3-19 Deposition of Elaine Louise Farvour
[34] 2-20-19 Life Care Plan, Robert Cooper MD
[35] 7-3-19 Deposition of Elaine Louise Farvour

Hobbies and Leisure Time Activities

Mr. Farvour's previous hobbies included travel, spending time with his family, going into the woods to walk and drive, yard work, gardening, walking his dogs and keeping up with the news. Ms. Farvour reports that Mr. Farvour's current hobbies are limited to spending time with this grandchildren and daughters as well as working in the yard and garden.[36]

Preliminary Life Care Plan Conclusions and Opinions

Careful consideration has been given to medical, psychosocial, rehabilitation, and deposition data made available to prepare Mr. Farvour's Life Care Plan. It is my professional opinion that more likely than not the needs and costs outlined in Mr. Farvour's Life Care Plan (Attachment A, Summary of Lifetime Costs) are required based on his clinical and disability status.

As noted, finalization of Mr. Farvour's future medical needs is pending. His preliminary future medical care, planned future medical/surgical care, therapeutic modalities, medical and diagnostic studies, radiation therapy, medications, medical supplies, wheelchair and mobility needs, medical equipment needs, aids for independent function, attendant care needs, home accessibility needs and transportation needs are defined in Attachment A.

Mr. Robert Farvour's Life Care Plan recommendations are based on careful consideration of his medical status and are indicated on a more probable than not basis with the understanding that the interventions will be implemented to mitigate health complications, lifetime needs and associated costs by provision of appropriate goods, services and support at the appropriate time.

Respectfully submitted,

Dana Penilton RN July 29, 2019
Dana Penilton RN, BSN, CCM, CLCP
Certified Life Care Planner
Certified Medical Case Manager

Attachment A: **Preliminary** Summary of Lifetime and Annual Charges

I declare under penalty of perjury under the laws of the state of Washington that the foregoing is true and correct.
Dated: July 29, 2019 at Portland, Oregon

Printed Name: Dana Penilton RN, BSN, CCM, CLCP

[36] 7-3-19 Deposition of Elaine Louise Farvour

Attachment A
Preliminary Summary of Lifetime and Annual Charges

Re: Robert Delano Farvour
Address: 207 Sparks Dr. Kelso, WA

Date of Birth: [redacted]1950 (68-69 years old)
Date of Diagnosis: February 16, 2017
Date of Report: July 29, 2019

Mr. Robert Delano Farvour's Life Care Plan is being completed at the request of Whitney Passmore, Esq. A Life Care Plan is intended to be a dynamic document and this plan is intended to be revised and updated to reflect Mr. Farvour's medical condition changes, medical complications, response to treatment and the clinical impact of his medical condition upon his health and well-being. Life Care Planning is a comprehensive, multi-disciplinary approach[1,2] which systematically documents the needs of a person after a catastrophic event in addition to projecting costs for needed goods and services over an estimated life-span. The objective of Life Care Planning is to maximize a person's independence, functional abilities, community access, mental well-being and quality of life as well as promote vocational and/or leisure and productive activities[3,4,5] within the parameters of an injury/illness. Mr. Farvour expressed that his goal to spend time with his daughters and grandchildren. Life Care Plan recommendations are based on careful consideration of Mr. Farvour's clinical status, are indicated on a more likely than not basis, have been determined to be medically necessary based on medical evidence with the understanding that the interventions will be implemented to mitigate health complications, lifetime needs and associated costs by provision of appropriate goods, services and support at the appropriate time.

It needs to be noted that Mr. Farvour's life care plan is preliminary to assist Ms. Passmore with mediation scheduled prior to my retention. Mr. Farvour's life care plan is being completed in adherence with Life Care Plan Standards of Practice and Life Care Planning Consensus and Majority

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[1] Pennachio F., Merritt J.L. (2014, September). Working Together Physiatrist & Life Care Planner in Developing a Comprehensive LCP. *International Symposium on Life Care Planning.* Lecture conducted from Minneapolis, Minnesota.
[2] Masterson J., Woodard L., Mitchell N., Penilton D., Smolarski R., Mertes A., Marcinko D., Thomas K., Turner D. (2019). International Academy of Life Care Planners' position paper on transdisciplinary practice. *Journal of Life Care Planning.* 17 (2): 3-4.
[3] International Association of Rehabilitation Professionals (IARP) and International Academy of Life care Planners (IALCP), The Life Care Planning Section of the International Association of Rehabilitation Professionals. (2015). Standards of Practice for Life Care Planners.
[4] Johnson, C., Pomaranz J., Stetten N. Consensus and majority statements derived from Life Care Planning Summits held in 2000, 2002, 2004, 2006, 2008, 20109, 2012, 2015 and 2017 and updated via Delphi study in 2018. *Journal of Life Care Planning.* 2018; 16(4): 15-18.
[5] Steward, D., Reid C., Riddick-Grisham, S., Cyphers, G. (2014, September) The Importance of Productive Activity in Life Care Planning. *International Symposium on Life Care Planning.* Lecture conducted from Minneapolis, MN.

Statements (best practices) however, development of his life care plan remains 'in process' therefore this report is preliminary. Review of available medical records was completed although finalization of life care plan cannot be completed until updated documentation is available as the most recent medical report was dated 5-4-18. Collaboration with medical specialists to be retained by Ms. Passmore is pending and required prior to completing Mr. Farvour's life care plan. Ms. Passmore was informed of my request to complete onsite assessment on 4-10-19; as of the time of the preliminary life care plan this decision remained pending. Review of research, literature and treatment guidelines related to Mr. Farvour's clinical status was initiated; this will be completed when current medical records are available for review and analysis. I reserve the right to amend or supplement this report if additional clinical or medical information becomes available or Mr. Farvour's clinical status changes.

Mr. Farvour's Life Care Plan is based on a life expectancy of 4 years (reduced from15.8 years). The reduction in life expectancy is based on plaintiff physician expert Robert Cooper MD, FAAPMR opinion on reduced life expectancy.[6,7] Consultation with physician experts to be retained by Ms. Passmore for an opinion regarding Mr. Farvour's life expectancy is pending. The costs defined in this report are based on researched charges, current charges, invoiced charges, or estimated costs based on experience, therefore, inflationary or growth factors are not reflected in the document. It is recommended that an economist be consulted for adjustment of inflation, projection of the value of the costs and services over time, and a determination of present value.

Mr. Farvour's anticipated medical care and treatment costs related to his diagnosis of malignant neoplasm of prostate[8] and secondary malignant neoplasm of bone[9] are defined in Life Care Plan Attachment A. The following precepts apply to the calculations included in the summary of lifetime and annual charges:

1. Begin and end dates are inclusive, for example; 2019-2020 (Year 1 + Year 1 to Year 2) = 2 years/24 Months (2019=year 1, 2019-2020=year 2, etc.)
2. Treatment modalities with a start and end date are calculated based on inclusive years as described in precept number one.
3. The dates for this report indicate a full twelve month period starting with the first day of plan implementation and ending at the life expectancy of the individual.

[6] Arias E. Xu J. 2015 National Vital Statistics Report. Vol. 67, No. 7, published November 13, 2018 https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_07-508.pdf Retrieved 3-2-19
[7] 2-20-19 Life Care Plan prepared for Mr. Robert Farvour, Robert Cooper MD, FAAPMR
[8] 2-16-17 PeaceHealth, Pathology, Naquib Osman Laila MD
[9] 3-3-17 Nuclear Medicine, Bone Single-photon emission computed tomography (SPECT), Hasan Osman MD

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
PROJECTED EVALUATIONS							
Speech and Language Pathology Evaluation 92523	NA	NA	NA	$0.00	$0.00	NA	Re-evaluation of dysphagia (sensation foods/liquids obstructed when swallowing) and hypophonia and determination if speech and language pathology therapy indicated.[10,11,12] After treatment with Cymetra injections, Karen Drake MD noted on 9-20-17 that further voice therapy was not anticipated at this time.[13] NOTE: If current medical records reveal treatment patterns beyond what review of available documentation defines, reconsideration of recommendation is warranted.
FUTURE MEDICAL CARE							
Primary Care Physician 99496, 99223, 99214, 99204, 99213, 99215	2019	LE	3 visits per year	$381.00 per visit	$1,143.00	TBD by economist	2017 is the most recent historical and billing documentation of Michael Bartlett MD, primary care physician follow up. Dr. Bartlett treated Mr. Bartlett for sequela secondary to malignant neoplasm of prostate and secondary malignant neoplasm of bone.[14,15]
Radiation Oncologist Choong Kim MD Zafer Yildirim MD	2019	LE	Option 1 1-2 per year Ave 1.5 per year	$351.20 per visit	Option 1 $526.80 per year	TBD by economist	Based on available billing trends and medical records, radiation oncology follow up was 2-5 times per month when Mr. Farvour was actively participating in palliative radiation treatment.[16,17] Records indicate the final palliative radiation

[10] 5-11-17 Speech Therapy Initial Evaluation, Allison Munkelwitz, CCC-SLP
[11] 6-8-17 OHSU, Paul Flint MD, ENG
[12] 6-8-17 OHSU Voice Evaluation, Karen Drake MA, CCC
[13] 9-20-17 OHSU Orders, Karen Drake MD
[14] 4-28-17 Michael Bartlett MD
[15] 6-2-17 Progress Note Michael Bartlett MD
[16] 3-13-17 Urology Progress Note, John Mansfield MD
[17] 3-21-17 PeaceHealth Radiation Oncology Progress Note, Choong Kim MD

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
71260, 74177 99215, 99204, 99213, 99215			Option 2 2-5 visits per month Ave 3.5/visits per month		Option 2 $14,750.40 per year		treatments were completed on 4-4-18 and 5-4-18.[18] Response to 5-4-18 treatment (right upper back) revealed pain well managed with Fentanyl patch.[19] Option 1 reflects radiation follow up 1-2 visits per year Option 2 reflects 3.5 visits per month reflecting active palliative radiation treatment.
Urologist John Mansfield MD 99204, 99213, 99215, 51702, 99214	2019	LE	1-3 visits per year Ave 2 visits per year	$206.60 per visit	$413.20 per year	TBD by economist	The most recent medical documentation of urology follow up is 3-13-17 in which follow up was recommended in 4 months.[20] Based on available billing and medical documentation, it appears urology follow up ranges between 1-3 times per year.
Otolaryngologist Paul Flint MD Karen Drake MD 99214, 99204, 99213, 99215	2019	LE	3 visits per year	$304.25 per visit	$912.75 per year	TBD by economist	Ongoing monitoring and management of right-sided vocal cord paralysis[21,22] and dysphagia.[23] Available medical documentation reflects that over the course of 2017 there were 3 otolaryngology appointments.
Psychology 90791-90792 90832-90847	Burst therapy varies based on an individual's preferences and may occur with a group of appointments over a period of time followed by a period of minimal or no			~$130.00 to $160.00 per session	Unknown	Unknown	In addition to facing the diagnosis of prostatic adenocarcinoma with metastasis, Mr. Farvour and his wife are dealing with changes within their relationship which impacts their bond as husband

[18] 4-4-18 Radiation Oncology Follow Up Note, Choong Kim MD
[19] 5-4-18 Radiation Oncology Follow Up Note, Choong Kim MD
[20] 3-13-17 Urology Progress Note, John Mansfield MD
[21] 4-26-17 PeaceHealth Radiation Oncology Progress Note, Choong Kim MD
[22] 4-27-17 PeaceHealth, Jeffery Davis MD, Otolaryngology
[23] 4-28-17 Michael Bartlett MD

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
	treatment. The number of burst therapy cycles is anticipated to vary. It is suggested that treatment should include individual sessions for Mr. Farvour and Ms. Farvour as well as couples therapy. 1-2 per week for 3-12 months Total 12-104 sessions over LE Preliminary Range $1,740.00 to $15,080.00 NOTE: Calculations based on 52.14 weeks per year NOTE: Information provided for informational purposes.						and wife. Patients and families facing advancing cancer deal with preparatory grief and/or psychological distress (revealed as depression and anxiety). Mr. Farvour and his wife cannot be adequately assessed without access to complete life care plan assessment and/or updated medical records.[24] Finalizing psychological services for Mr. Farvour and his wife requires medical insight. Treatment guidelines and American Psychiatric Association position statements (back to 1974) were researched without finding treatment guidelines related to cancer care, therefore, input from psychologists specializing in working with people/couples with situations similar to Mr. Farvour's is recommended. Potential psychological treatment alternatives are defined based on consultation with specialists when working with people in similar situations. Psychological treatment in situations similar to the Farvour family is often implemented in bursts rather than continuously.
PLANNED FUTURE MEDICAL/SURGICAL NEEDS							
Cymetra Injection	Unknown	Unknown	Unknown	$0.00	$0.00	Unknown	Cymetra is an injectable material made from cadaver skin and used to treat vocal cord paralysis.[25,26] Mr. Farvour received Cymetra

[24] Mystakidou K., Parpa E., Tsilika E. (2007). Preparatory grief, psychological distress and hopelessness in advanced cancer patients. *European Journal of Cancer Care*. 17(2):145-151. https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2354.2007.00825.x Retrieved 5-28-19.
[25] Karpenko A., Dworkin J., Meleca R., Stachler R. Cymetra injection for unilateral vocal fold paralysis. *Annals Otology Rhinology Laryngology*. 2003; 112, 11:927-34. https://www.ncbi.nlm.nih.gov/pubmed/14653360 Retrieved 4-12-19
[26] University of Iowa Health Care (UIHC). (2019) *Iowa Head and Neck Protocols: Unilateral Laryngeal Paralysis or Vocal Cord Paralysis.*

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
							injection for severe vocal impairment secondary to vocal cord paralysis, completed 6-12-17. Karen Drake MD indicated further voice treatment was not indicated.[27]
Palliative Radiation Treatment 78320, A9503, 77280, 77292, 77300, 77387, 77412	Unknown	Unknown	Option 1 No treatment Option 2 Treatment to one body part, 10-15 treatments per session	Option 2 *Low Cost* $1,515.00 per session *High Cost* $6,083.00 per session	Option 1 $0.00 Option 2 Range $1,515.00 per year to $6,083.00 per year	Unknown	Mr. Farvour has received palliative radiation treatment to: base of skull, T9-L1 vertebral bodies, bilateral hips, shoulder and upper back.[28,29, 30,31,32] The most recent palliative treatment focused on right shoulder and between 2-1-18 and 2-23-18, fifteen treatments were rendered.[33] On 5-4-18 Choong Kim MD noted Mr. Farvour reported pain was well controlled with Fentanyl patch.[34] It is unknown if Mr. Farvour will pursue additional palliative radiation treatment. Option 1 reflects no additional palliative radiation treatment Option 2 reflects continued treatment as reflected in 2018 treatment documentation. Note: If updated medical documentation reveals treatment beyond one body part, 10-15 sessions per treatment series, reconsideration of recommendation is warranted.

[27] 6-12-17 OHSU Orders, Karen Drake MD
[28] 4-25-18 Radiation Oncology Follow Up Note, Choong Kim MD
[29] 4-4-18 Radiation Oncology Follow Up Note, Choong Kim MD
[30] 2-23-18 Radiation Oncology Follow Up Note, Choong Kim MD
[31] 2-21-18 Radiation Oncology Follow Up Note, Choong Kim MD
[32] 1-26-18 Radiation Oncology Follow Up Note, Choong Kim MD
[33] 2-23-18 Radiation Oncology Follow Up Note, Choong Kim MD
[34] 5-4-18 Radiation Oncology Follow Up Note, Choong Kim MD

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
PROJECTED THERAPEUTIC MODALITIES							
Outpatient Speech and Language Pathology (SLP) 92523, 92523, 92521, 92507, 96125, 97532	NA	NA	NA	Evaluation $397.00 Follow up $113.00 per 15 minute increment	$0.00	NA	SLP treatment implemented for dysphagia and hypophonia. [35,36,37] After treatment with Cymetra injections Karen Drake MD noted on 9-20-17 that further voice therapy was not anticipated at this time.[38] NOTE: Available medical documentation reveals there has been no further SLP treatment; however, if SLP was reinitiated, reconsideration of SLP recommendation is warranted.
Outpatient Physical Therapy 97163, 97110, 97140, 97112	NA	NA	NA	Evaluation $170.00-$250.00 per session Follow up $88.00-$113.00 per 15 minute increment	$0.00	NA	Clifford Schostal MD evaluated Mr. Farvour on 3-22-18 noting dependent polyneuropathy, orthostasis possibly due to polyneuropathy with slight autonomic impairment although not requiring treatment. It was noted that if treatable cause could not be identified, gait training would be recommended.[39] Available medical records did not document if physical therapy completed or if clinical status warrants gait training. NOTE: LCP methodology notes that recommendations should not include possible treatment (50% or less). Cost information is provided for informational purposes only.

[35] 5-11-17 Speech Therapy Initial Evaluation, Allison Munkelwitz, CCC-SLP
[36] 6-8-17 OHSU, Paul Flint MD, ENG
[37] 6-8-17 OHSU Voice Evaluation, Karen Drake MA, CCC
[38] 9-20-17 OHSU Orders, Karen Drake MD
[39] 3-22-18 Progress Notes, Clifford Schostal MD

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
MEDICAL AND DIAGNOSTIC STUDIES							
Single-photon Emission Computed Tomography (SPECT)/Bone Scan 78320, A9503	Unknown	Unknown	Once per year	$1,528.70 (includes oncology radiologist reading images)	$1,528.70	Unknown	3-3-17 SPECT scan revealed widespread focal abnormalities through skeleton consistent with metastatic disease to the bone.[40] There are no medical records beyond 5-4-18, however, Robert Cooper MD noted a 7-17-18 bone scan had been completed. Clinical Practice Guidelines for malignant neoplasm of the bone indicate plain radiographs are insensitive to test for metastasis recommending instead radionuclide bone scan.[41,42] Defining frequency of SPECT scan follow up is based historical treatment patterns in available medical records. NOTE: If current medical records reveal treatment patterns beyond what review of available documentation defines, reconsideration of recommendation is warranted.
CT Cervical Spine with and without contrast 72127	Unknown	Unknown	Not enough data to make a determination	$867.00 (includes oncology radiologist reading images)	Unknown	Unknown	Mr. Farvour underwent CT scan of his neck for vocal cord evaluation on 4-20-17. Findings revealed unremarkable nasopharyngeal soft tissue structures.[43] Available medical records do not reflect additional CT of cervical spine studies since then. Published treatment guidelines for management of vocal cord paralysis were not identified, however, Mayo Clinic Patient Health

[40] 3-3-17 Nuclear Medicine, Bone Single-photon emission computed tomography (SPECT), Hasan Osman MD
[41] Coleman R., Body J., Aapro M., Hadji P., Herrstedt J. (2014). Bone health in cancer patients: European Society for Medical Oncology (ESMO) Clinical Practice Guidelines. *Annals of Oncology*. 25(Supplement 3): iii124-iii137. https://watermark.silverchair.com Retrieved 5-15-19
[42] Vyngaert T., Stobel K., Kampen W., Kuwer T., van der Bruggen W., Mohan H., Gnanasegaran G., Delgado-Bolton R., Weber W., Beheshti M., Langsteger W., Giammarile F., Mottaghy F., Paycha F. (2016). The European Association of Nuclear Medicine (EANM) practice guidelines for bone scintigraphy. *European Journal of Nuclear Medicine and Molecular Imaging*. 43:1723-1738. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4932135/ Retrieved 5-15-19.
[43] 4-20-17 PeaceHealth CT Neck Soft Tissue w/ Contrast

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
							Information indicates imaging may be appropriate if nerve injury is thought to be the cause.[44] Paul Flint MD, ENG diagnosed right vocal fold motion impairment secondary to brain stem metastasis, identifying the etiology of Mr. Farvour's vocal cord paralysis.[45] Without more data, determination of ongoing need for Cervical CT scanning cannot be made. If current medical records reveal additional Cervical CT scanning, consideration of recommendation is warranted. NOTE: Cost information provided for informational purposes.
Swallow Evaluation 92610	Unknown	Unknown	Not enough data to make a determination	$665.00 (includes SLP evaluation and swallow evaluation)	Unknown	Unknown	Swallow evaluation was initially utilized to evaluate the status of Mr. Farvour's moderate pharyngeal phase dysphagia after which additional diagnostic evaluation was recommended.[46] Flexible fiberoptic laryngoscopy with videostroboscopy revealed right vocal fold motion impairment secondary to brain stem metastasis, unilateral complete paralysis of vocal cord and dysphonia were diagnoses.[47,48] Available medical records do not document a repeat swallow study evaluation. Without current medical records, determination of whether or not repeat swallowing evaluation is indicated cannot be determined. NOTE: Cost information provided for informational purposes.

[44] Mayo Clinic, Patient Care & Health Information: Vocal cord paralysis. https://www.mayoclinic.org/diseases-conditions/vocal-cord-paralysis/diagnosis-treatment/drc-20378878 Retrieved 5-16-19.
[45] 6-8-17 OHSU, Paul Flint MD, ENG
[46] 5-11-17 Speech Therapy Initial Evaluation, Allison Munkelwitz, CCC-SLP
[47] 6-8-17 OHSU, Paul Flint MD, ENG
[48] 6-8-17 OHSU Voice Evaluation, Karen Drake MA, CCC

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
Laryngoscopy 31575	Unknown	Unknown	Not enough data to make a determination	$250.00	Unknown	Unknown	4-27-17 Laryngoscopy[49] revealed oropharynx, hypopharynx and supraglottis with no masses or lesions and complete paralysis or right vocal cord with no evidence of lesion.[50] This was followed by higher level of diagnostics-- flexible fiberoptic laryngoscopy with videostroboscopy[51] which revealed right vocal fold motion impairment secondary to brain stem metastasis. [52,53] Available medical records do not document repeat laryngoscopy. Without current medical records, determination of whether or not repeat laryngoscopy is indicated cannot be determined. NOTE: Cost information provided for informational purposes.
Flexible fiberoptic laryngoscopy with videostroboscopy 31575, 31579	Unknown	Unknown	Not enough data to make a determination	$450.00	Unknown	Unknown	Flexible fiberoptic laryngoscopy with videostroboscopy revealed right vocal fold motion impairment secondary to brain stem metastasis. Karen Drake MA, CCC diagnosed unilateral complete paralysis of vocal cord and dysphonia which ultimately resulted in Dr. Flint recommending Cymetra injection. [54,55] Available medical records do not document repeat flexible fiberoptic laryngoscopy with videostroboscopy.

[49] Laryngoscopy: Either rigid telescope (does not allow patient to produce sound as component of examination) or flexible fiberoptic scope (allows observation of vocal cords while the patient makes sound) to examine the larynx (voice box) and vocal cords.
[50] 4-27-17 PeaceHealth, Jeffery Davis MD, Otolaryngology
[51] Flexible fiberoptic laryngoscopy with videostroboscopy: State-of-the-art technology in which rigid endoscopy passed through the mouth or flexible endoscopy passed through the nose while stroboscopy scope is introduced along the tongue towards the back of the mouth or via thin flexible endoscopy passed through the nose and suspended in the throat to examine the of larynx and vocal cords . The exam allows detection of vibratory asymmetries, motion of vocal cord movements and can detect conditions potentially not visible under continuous light and is digitally recorded.
[52] 6-8-17 OHSU, Paul Flint MD, ENG
[53] 6-8-17 OHSU Voice Evaluation, Karen Drake MA, CCC
[54] 6-8-17 OHSU, Paul Flint MD, ENG
[55] 6-8-17 OHSU Voice Evaluation, Karen Drake MA, CCC

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
							Without current medical records, determination of whether or not repeat swallowing evaluation is indicated cannot be determined. NOTE: Cost information provided for informational purposes.
External Beam Radiation Therapy (EBRT) Simulation (Defines relevant normal and abnormal target anatomy to define exact treatment position.) 77280 Simulation simple, single treatment area 77285 Simulation intermediate, two separate treatment areas 77290 Simulation, complex three or more treatment areas Dosimetry Calculation (Calculation of absorbed dose and optimization of dose delivery.) 77300 Dosimetry calculation Radiation Treatment Delivery (Linear accelerator (linac) delivers high-energy rays (beams) aimed into tumor) 77401-77416-delivery Contrast Infusion G6003 Treatment delivery to single area G6014: Treatment delivery to 3 or more areas NOTE: CPT 77300 (Dosimetry calculation) This code is no longer valid and bundled into codes 77306, 77316, 77317 and 77318 used for therapy isodose planning.			Not enough data to make a determination	Simulation 77280 $1,057.00 77290 $2,610.00 Radiation Treatment Delivery (Includes radiation oncologist time) 77401-77416 ~$4055.01[56] Dosimetry Calculation 77300 $3,416.00 Contrast Infusion Q9957 $335.00 Magnetic Resonance (Proton) Imaging w-w/o Contrast 72157-72158 ~$1,174.00 to $1,734.75 Simulation + EBRT ~$1404.72 Note: Estimated costs (~) are based on published literature describing simple to complex EBRT treatment.[57]		Unknown	Mr. Farvour reported excruciating hip pain, right shoulder and mid-back pain managed by Choong Kim MD with palliative radiation therapy.[58,59,60] Over 2017 and 2018 Choong Kim MD radiation oncologist administered radiation oncology treatment (External Beam Radiation Therapy [EBRT]) to lower cervical spine and right superior scapula (10 treatments), base of skull (x 2 for 10 treatments each cycle), bilateral hips (x 2, 10 treatments each cycle), humerus (15 treatments) and T9-L1 vertebral bodies (10 treatments). EBRT varied from simple (treatment to one target area) to complex (treatment to 3 or more target areas).[61,62,63] Available medical records do not document if EBRT has been reinitiated and if so the number of areas treated at a time (complexity) or frequency of treatment. EBRT treatment for bone pain is endorsed by treatment guidelines.[64,65] Without current medical records and physician

[56] Bauer-Nilson K., Hill C., Trifiletti D., Libby B., Lash D., Lain M., Christodoulou D., Hodge C., Showalter T. (2018). Evaluation of delivery costs for external beam radiation therapy and brachytherapy for locally advanced cervical cancer using time-driven activity-based costing. *International Journal Radiation Oncology Biology, Physics.* 100(1):88-94. Abstract. https://www.ncbi.nlm.nih.gov/pubmed/29079120 Retrieved 4-21-19

[57] Bauer-Nilson D., Hill C., Trifiletti D., Libby B., Lash D., Lain M., Christodoulou D., Hodge C., Showalter T. (2018). Evaluation of delivery costs for external beam radiation therapy and brachytherapy for locally advanced cervical cancer using time-driven activity-based costing. *Int Journal Radiat Oncology Biol Phys.* 100(1): 88-94. https://www.ncbi.nlm.nih.gov/pubmed/29079120 Retrieved 5-28-19.

[58] 3-21-17 PeaceHealth Radiation Oncology Progress Note, Choong Kim MD

[59] 6-26-17 Radiation Oncology Follow Up Note, Choong Kim MD

[60] 10-11-17 Radiation Oncology Follow Up Note, Choong Kim MD

[61] 5-22-17 End of Radiation Treatment Note, Choong Kim MD

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
							input, determination of whether or not EBRT is indicated cannot be determined. NOTE: Cost information provided for informational purposes and includes simulation, delivery and contrast infusion. Note: Costs defined with (incomplete) billing correlated with medical records based on historical treatment patterns or potential treatment if EBT reinitiated.
MEDICATIONS							
Duragesic Patch (Fentanyl Patch)	2019	LE	75 mcg patch Replace every 3 days 10 patches per month	$401.99 per month	$4,823.88	TBD by economist	Mr. Farvour reports excruciating hip pain, right shoulder and mid-back pain managed by Choong Kim MD.[66,67,68] Utilization of opiods for management of cancer related pain endorsed by treatment guidelines.[69]
Morphine Sulfate IR	2019	LE	15 mg as needed current utilization 3/day 90 tablets per month	$46.49 per month	$557.88	TBD by economist	Mr. Farvour reports excruciating hip pain, right shoulder and mid-back pain managed by Choong Kim MD.[70,71,72] Utilization of opiods for management of cancer related pain endorsed by treatment guidelines.[73]

[62] 6-26-17 Radiation Oncology Follow Up Note, Choong Kim MD
[63] 2-23-18 Radiation Oncology Follow Up Note, Choong Kim MD
[64] World Health Organization (WHO). (2018). *WHO Guidelines for The Pharmacological and Radiotherapeutic Management of Cancer Pain in Adults and Adolescents*. https://apps.who.int/iris/bitstream/handle/10665/279700/9789241550390-eng.pdf?ua=1 Retrieved 5-21-19.
[65] Mallor M., Giusti R., Aielli F., Hoskin P., Rolke R., Sharma M., Ripamonti C. (2018). Management of cancer pain in adult patients: ESMO (European Society for Medical Oncology) Clinical Practice Guidelines. *Annals of Oncology*. 29(Issue Supplement 4): IV166-iv191. https://academic.oup.com/annonc/article/29/Supplement_4/iv166/5046945 Retrieved 5-21-19.
[66] 3-21-17 PeaceHealth Radiation Oncology Progress Note, Choong Kim MD
[67] 6-26-17 Radiation Oncology Follow Up Note, Choong Kim MD
[68] 10-11-17 Radiation Oncology Follow Up Note, Choong Kim MD
[69] Mallor M., Giusti R., Aielli F., Hoskin P., Rolke R., Sharma M., Ripamonti C. (2018). Management of cancer pain in adult patients: ESMO (European Society for Medical Oncology) Clinical Practice Guidelines. *Annals of Oncology*. 29(Issue Supplement 4): IV166-iv191. https://academic.oup.com/annonc/article/29/Supplement_4/iv166/5046945 Retrieved 5-21-19.
[70] 3-21-17 PeaceHealth Radiation Oncology Progress Note, Choong Kim MD
[71] 6-26-17 Radiation Oncology Follow Up Note, Choong Kim MD
[72] 10-11-17 Radiation Oncology Follow Up Note, Choong Kim MD
[73] Mallor M., Giusti R., Aielli F., Hoskin P., Rolke R., Sharma M., Ripamonti C. (2018). Management of cancer pain in adult patients: ESMO (European Society for Medical Oncology) Clinical Practice Guidelines. *Annals of Oncology*. 29(Issue Supplement 4): IV166-iv191. https://academic.oup.com/annonc/article/29/Supplement_4/iv166/5046945 Retrieved 5-21-19.

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
Colace (Docusate sodium)	2019	LE	100 mg tablets Option 1 15 tabs per month Option 2 30 tablets per month	Option 1 $6.99/month Option 2 $13.99/month	Option 1 $83.88 Option 2 $167.88	TBD by economist	Stool softener indicated to counteract side effects of opioid medications. [74,75] No documentation on dosage or utilization is available. Preliminary LCP assumes 1 tablet every other day and 1 daily (Option 1 and 2). Cancer pain treatment guidelines endorse management of side effects of opioid medications.[76]
Luprom Injection (Leuprolide acetate) J9217	Unknown	Unknown	Advanced Pancreatic Cancer Dosing 7.5 mg/month 22.5 mg/3 months 30 mg/4 months 45 mg/6 months Mansfield MD: recommended re-injection 4 months after initial injection	$1,008.00 per injection Administration Fee $82.00 per injection	Unknown	Unknown	Prostate cancer causes androgen (male sex hormone) resistance which is theorized to cause resistant prostate cancer cells which multiply and advance the disease. Luprom is a hormone therapy agonist which blocks production of (luteinizing hormone releasing hormone [LHRH] resulting in reduction in testosterone release which contributes to tumor growth and progression. Lupron therapy is considered when cancer recurs after radiation therapy or surgery or with metastasis. Side effects can include increased bone pain and difficulty urinating. [77,78,79,80] John Mansfield MD urologist

[74] Swegle J., Logemann C. (2006). Management of common Opioid-induced adverse effects. *American Family Physician*. 74,8; 1347-1354. Abstract. https://web.a.ebscohost.com/abstract?direct=true&profile=ehost&scope=site&authtype=crawler&jrnl=0002838X&AN=23004458&h=%2bE54MgOiRV4V6QyZaVD040yfOy74TlkXhKSvMTxWjsUnIvUGe3xjvoNJc39KHdrWrCxNxyMOaqQZ5vBo2fHRAw%3d%3d&crl=c&resultNs=AdminWebAuth&resultLocal=ErrCrlNotAuth&crlhashurl=login.aspx%3fdirect%3dtrue%26profile%3dehost%26scope%3dsite%26authtype%3dcrawler%26jrnl%3d0002838X%26AN%3d23004458 Retrieved 5-27-19.

[75] Chen C., Kwok A., Xiang Bian Z., Tse D. (2013). A cross-sectional study of constipation and laxative use in advanced cancer patients: insights for revision of current practice. *Supportive Care in Cancer*. 21, 1; 149-156. Abstract. https://link.springer.com/article/10.1007/s00520-012-1504-x Retrieved 5-27-19.

[76] Mallor M., Giusti R., Aielli F., Hoskin P., Rolke R., Sharma M., Ripamonti C. (2018). Management of cancer pain in adult patients: ESMO (European Society for Medical Oncology) Clinical Practice Guidelines. *Annals of Oncology*. 29(Issue Supplement 4): IV166-iv191. https://academic.oup.com/annonc/article/29/Supplement_4/iv166/5046945 Retrieved 5-21-19.

[77] Sharafi N., Gulley J., Dahut W. (2005). Androgen deprivation therapy for prostate cancer. *JAMA*. 294(2):238-44. https://jamanetwork.com/journals/jama/fullarticle/201192?appId=scweb Retrieved 5-28-19.

[78] Garnick M. (2009). Hormone therapy for prostate cancer. *Harvard Health Publishing*, *Harvard Medical School*. https://www.health.harvard.edu/blog/hormone-therapy-for-prostate-cancer-2009031016 Retrieved 5-27-19.

[79] American Cancer Society medical and editorial content team. Hormone therapy for prostate therapy. *American Cancer Society*. https://www.cancer.org/cancer/prostate-cancer/treating/hormone-therapy.html Retrieved 5-27-19.

[80] Mayo Clinic Staff. Hormone therapy for prostate cancer. *Mayo Clinic*.

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
							administered Luprom recommending repeat injection four months later.[81] Available medical records do not document if Luprom injections were repeated or if treatment may be reinitiated. Consultation with medical specialists and access to current medical records recommended so recommendations can be finalized.
Celebrex	2019	LE	200 mg per day #30 tabs per month	$190.00 per month	$2,280.00	TBD by economist	Mr. Farvour reports excruciating hip pain, right shoulder and mid-back pain managed by Choong Kim MD.[82,83,84] It is understood that Celebrex is prescribed for pain management.
Melatonin	2019	LE	5 mg at bedtime (hs) #30 tabs per month	$2.37 per month	$28.44 per year	TBD by economist	Facilitate sleep. Melatonin is a hormone that regulates sleep-wake cycles and facilitates sleep. It is understood that Mr. Farvour struggles with sleep due to pain.
Mirtazapine (Remeron)	2019	LE	60 mg at night (hs) Available in 30 mg tablets #60 tablets per month	$99.80 per month	$1,197.60 per year	TBD by economist	Antidepressant medication understood to be prescribed for presumed depression related to diagnosis. Available medical documentation does not indicate that depression is a pre-existing condition.

[81] 3-13-17 Urology Progress Note, John Mansfield MD
[82] 3-21-17 PeaceHealth Radiation Oncology Progress Note, Choong Kim MD
[83] 6-26-17 Radiation Oncology Follow Up Note, Choong Kim MD
[84] 10-11-17 Radiation Oncology Follow Up Note, Choong Kim MD

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
MEDICAL SUPPLIES							
Foley Catheter and Supplies Healthcare Common Procedure Coding System HCPCS A4314: HCPCS A4315: catheter insertion tray with drainage bag with indwelling catheter 51702 RN visit- Insert indwelling catheter	Unknown	Unknown	Option 1 Once every 3 weeks Option 2 Once a week	Option 1 $164.39 per catheter change Option 2 $164.39 per catheter change (Catheter change costs reflects RN home visit and Foley Catheter kit)	Option 1 $2,857.09 Option 2 $8,571.29	Unknown	Bladder management. Limited medical records do not define Mr. Farvour's current bladder management needs. The only reference to bladder management is 2-10-17 billing information reflecting insertion of temporary indwelling Foley catheter (CPT 51702 code on billing) prior to transurethral resection of prostate (TURP) completed on 2-14-17.[85,86] Without current medical records and evaluation of whether or not Mr. Farvour's current bladder management program, final determination of bladder management is pended. Consultation with medical specialists and access to current medical records is indicated so recommendations can be finalized. For purposes of preliminary life care plan development and based on coding utilized by Robert Cooper MD, FAAPMR in 2-20-19 life care plan, for purposes of preliminary life care plan it is understood that Mr. Farvour's clinical status warrants an indwelling catheter (HCPCS code A4315: catheter insertion tray with drainage bag with indwelling catheter)[87]. Physicians vary in recommendations regarding frequency of indwelling catheter change ranging from weekly to

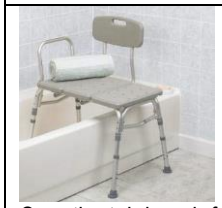
[85] 2-14-17 PeaceHealth Operative Report, Patrick Lassen MD
[86] Cravens D., Zweig S. (2000). Urinary catheter management. *American Family Physician. 61(2):369-376.*
[87] 2-20-19 Robert Cooper MD, FAAPMR, Life Care Plan, page 79

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
							every several weeks to whenever obstruction occurs.[88] Two preliminary LCP options are defined: Option 1: change indwelling catheter weekly Option 2: change indwelling catheter every 3 weeks If the catheter becomes obstructed it will require flushing and/or catheter change. For purposes of LCP calculation it is not possible to determine how frequently this may happen, therefore this potential cost is not included in LCP calculations. If Mr. Farvour is transitioned to intermittent catheterization program for bladder management, costs would need to be recalculated. Note: LCP calculations based on 52.14 weeks/year
ORTHOTICS/PROSTHETICS							
None anticipated							
WHEELCHAIR AND MOBILITY NEEDS							
Lightweight Manual Wheelchair	2019	LE	Every 5-10 years[89] One time over LE	$500.00	One time cost $500.00	TBD by economist	Medical documentation does not describe Mr. Farvour's mobility status, although it is not unreasonable to anticipate that mobility equipment would improve his independence and safety. Without current medical records, determination of whether or not a manual wheelchair is indicated cannot be determined with certainty. Manual wheelchair would facilitate

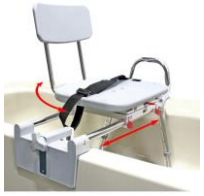
[88] Centers for Disease Control and Prevention (CDC). (2009). *Guideline for prevention of catheter-associated urinary tract infections.* https://www.cdc.gov/infectioncontrol/guidelines/cauti/index.html Retrieved 5-28-19.
[89] American Hospital Association (AHA). (2013). *Estimated Useful Lives of Depreciable Hospital Assets*.

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
							community access. Consultation with medical specialists and access to current medical records recommended so recommendations can be finalized.
 Invacare Tracer SX5  Quickie QXi  Quickie 2HP  Argon² Rigid lightweight active wheelchair							
Wheelchair Cushion	2019	LE	Every 5 years	$482.95 each	One time Cost $482.95	TBD by economist	Pressure relief, skin protection skin and prevent pressure wounds.
Cushion Cover	2019	LE	2 each year	$145.00 each	$290.00	TBD by economist	Allows one cushion cover to be laundered while the other used, facilitates hygiene.
Walker with Wheels, Brakes and Seat	2019	LE	Every 5-7 years One over LE	$54.99 each	One time cost $54.99	TBD by economist	Facilitate independence and safe mobility.
 Walker with wheels, brakes and seat							
Suitcase Portable Ramp	2019	LE	One over LE	$600.00 each	One time cost $600.00	TBD by economist	Allow access to non-barrier free areas and facilitate community access and participation in community.

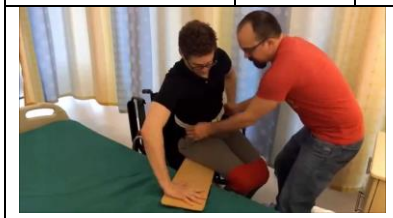
Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
OTHER EQUIPMENT NEEDS							
Full Electric Bed with Memory Foam Mattress	2019	LE	One time over LE	$899.00 each	One time cost $899.00	TBD by economist	Without current medical records, determination of whether or not a full electric bed is indicated cannot be determined with certainty. Full electric bed with memory foam mattress to facilitate comfort and mobility in bed. Consultation with medical specialists and access to current medical records recommended so recommendations can be finalized.
AIDS FOR INDEPENDENT FUNCTION							
Hand-held Shower Head	2019	LE	One time over LE	$44.98 each + $50.00 installation fee	One time cost $97.98	TBD by economist	Facilitate independence with hygiene.
Bath Bench/Shower chair	2019	LE	One time over LE	$267.00 each	One time cost $267.00	TBD by economist	Without the opportunity to complete in home life care plan assessment, it is not possible to determine bathroom access needs. A shower/bath bench facilitates safety. Consultation with medical specialists and access to current medical records is recommended so recommendations can be finalized.



Over the tub bench for sit-slide transfer



Sliding swivel seat to facilitate entry/exit from tub/shower

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
Toilet Safety Frame	2019	LE	One time over LE	$37.46 each (installation fee included with shower head installation cost)	One time cost $37.46	TBD by economist	Facilitate safety and independence.
Gait belt	2019	LE	One time over LE	$32.33 each	One time cost $32.33	TBD by economist	Facilitate safe transfers and ambulation.
  Gait Belt							
Sliding Transfer Board	2019	LE	One time over LE	$46.19	One time cost $46.19	TBD by economist	Facilitate safety with transfers, especially if Mr. Farvour is feeling weak or unwell.
  Sliding transfer board							
Life Alert	2019	LE	One time installation Monthly service fee	$315.00 $41.00 per month	One time cost $315.00 $492.00 per year	TBD by economist	Maximizes independence and provides ability to summon services if Mr. Farvour needs assistance and a caregiver is not present.

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
Reachers	2019	LE	3 every 5 years One time over LE	$20.35 each	One time cost $61.05	TBD by economist	Facilitates safety and independence. Provision of three reachers allows placement in different rooms.
 Reacher							
HEALTH & STRENGTH MAINTENANCE							
None identified							
ATTENDANT CARE/NURSING CARE/ASSISTANCE NEEDS							
Attendant Care	Unknown	Unknown	$27.00 per hour to $36.00 per hour Average $31.50 per hour Assumes 3 hours minimum shift <u>Option 1</u> 3 hours/day to assist with activities of daily living $34,492.50/year <u>Option 2</u> 3 hours in morning and 3 hours in evening to assist with morning care and getting ready for bed. 6 hours per day $68,985.00/year			Unknown	Without current medical records, determination of whether or not and to what extent Mr. Farvour requires attendant care cannot be determined. Consultation with medical specialists and access to current medical records is recommended so recommendations can be finalized. Mr. Farvour may benefit from non-skilled attendant care to assist with activities of daily living such as dressing and hygiene. For purposes of preliminary LCP, attendant care alternatives are presented in two options, however, recommendations cannot be finalized until additional information regarding Mr. Farvour's clinical status, ability to complete activities of daily living and attendant care needs is available.
Skilled Nursing Care	Unknown	Unknown	NA	NA	Unknown	Unknown	Without current medical records, determination of whether or not and to what extent Mr. Farvour requires skilled nursing care cannot be

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
							determined. Consultation with medical specialists and access to current medical records is recommended so recommendations can be finalized. If Mr. Farvour is using indwelling Foley catheter for bladder management, catheter changes require skilled nursing. Costs for this are accounted for under Foley Catheter and Supplies which define bladder management.
Housekeeping Assistance	Unknown	Unknown	Not enough data to make a determination	$35.00 to $50.00 per hour Ave $42.50/hour 1-4 hours per week Preliminary Range $2,215.95.00 to $8,863.80 per year		Unknown	Without current medical records, determination of whether or not and to what extent Mr. Farvour requires housekeeping assistance cannot be determined. Consultation with medical specialists and access to current medical records is recommended so recommendations can be finalized. Note: Costs defined for informational purposes. Note: Costs based on 52.14 weeks per year.
Yard and Home Maintenance	Unknown	Unknown	Not enough data to make determination	$150.00 to $185.00 per month Ave $167.50/month May through September (5 months per year) Preliminary Cost $837.50/year		Unknown	Without current medical records, determination of whether or not and to what extent Mr. Farvour requires yard and home maintenance cannot be determined. Consultation with medical specialists and access to current medical records is recommended so recommendations can be finalized. Note: Costs defined for informational purposes. Note: Costs based on 52.14 weeks per year.

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
ARCHITECTURAL/ACCESSIBLITY NEEDS							
Home Modifications	Unknown	Unknown	One time	The Veterans Administration's (VA)[90] Special Home Adaptation (SHA) grant[91] may be approved for disabled service members up to maximum of $13,511.00. The VA Housing Grant for Disabled Veterans may grant up to maximum $67,555.00.[92] Preliminary Range Estimate $13,511.00 to $67,555.00 Note: Utilization of VA grants for service members is referenced for cost analysis only, there is no assumption	Unknown	Without current medical records, determination of extent to which Mr. Farvour requires home modification for wheelchair access (if it is determined wheelchair mobility within the home is indicated) cannot be determined. Assessment of home configuration, delineation of mobility issues, consultation with medical specialists and access to current medical records is recommended so recommendations can be finalized. Wheelchair access may include entry/exit ramp(s), door widening, removal or carpets and replacement with smooth floors, bathroom, kitchen, bedroom modification, hand rails and grab bar installation, etc. Without the ability to complete home accessibility assessment and consult with home access modification specialists familiar with

[90] https://www.va.gov/opa/publications/benefits_book/benefits_chap02.asp Retrieved 12-31-18

[91] To be determined eligible for Special Home Adaptation grant permanent and total disability must be due to

1. Blindness in both eyes with 20/200 visual acuity or less.
2. Anatomical loss or loss of use of both hands.
3. Severe burn injuries.

[92] To be determined eligible for Housing Grant for Disabled Veterans permanent and total disability must be due to

1. Loss or loss of use of both lower extremities, which so affects the functions of balance or propulsion to preclude ambulating without the aid of braces, crutches, canes or a wheelchair.
2. Loss or loss of use of both upper extremities at or above the elbow.
3. Blindness in both eyes, having only light perception, plus loss or loss of use of one lower extremity.
4. Loss or loss of use of one lower extremity together with (a) residuals of organic disease or injury, or (b) the loss or loss of use of one upper extremity which so affects the functions of balance or propulsion as to preclude locomotion without the use of braces, canes, crutches or a wheelchair.
5. Severe burn injuries, which are defined as full thickness or subdermal burns that have resulted in contractures with limitation of motion of two or more extremities or of at least one extremity and the trunk.
6. The loss, or loss of use of one or more lower extremities due to service on or after Sept. 11, 2001, which so affects the functions of balance or propulsion as to preclude ambulating without the aid of braces, crutches, canes, or a wheelchair.

Treatment Modality	Year Initiated	Year Suspended	Frequency or replacement schedule	Cost per item/ visit	Annual Cost	Total Cost	Comments
				that Mr. Farvour should or would apply to or qualify for these grants.			American National Standards Institute (ANSI) to define home access needs and construction costs, reference to home modification allowances for service members can provide some guidance. Note: Costs defined for informational purposes.
EDUCATIONAL / VOCATIONAL NEEDS							
Refer to Vocational Rehabilitation Counselor if indicated.							
TRANSPORTATION NEEDS							
Transportation Assistance	Unknown	Unknown	Not enough data to make determination	NA	Unknown	Unknown	Without current medical records, determination of extent to which Mr. Farvour requires transportation assistance cannot be determined. Assessment of mobility issues, consultation with medical specialists and access to current medical records is recommended so recommendations can be finalized.
Format for LCP charts adapted from Guide to Rehabilitation. Copyright © 1989. Paul M. Deutsch & Associates.							

Respectfully submitted,

Dana Penilton RN
Dana Penilton RN, BSN, CCM, CLCP
Certified Life Care Planner
Certified Medical Case Manager

I declare under penalty of perjury under the laws of the state of Washington that the foregoing is true and correct.
Dated: July 29, 2019 at Portland, Oregon

Printed Name: Dana Penilton RN, BSN, CCM, CLCP

DANA PENILTON, RN, BSN, CCM, CLCP
Curriculum Vitae

Dana Penilton Consulting, Inc.
6312 SW Capitol Hwy. #418 Portland, Oregon 97239-1937
Cell [redacted] FAX [redacted]
email: danapen@comcast.net www.danapenilton.com

PROFESSIONAL CERTIFICATIONS and LICENSES

National Certification: Certified Life Care Planner; International Commission on Health Care Certification (ICHCC), 2002 to present
National Certification: Board Certified Case Manager; Commission for Certified Manager Certification (CCMC)
1996 to present
Oregon State Registered Nursing License, 1987 to present
Alaska State Registered Nursing License, 2008 to present
Washington State Registered Nursing License, 2000 to present
Idaho State Registered Nursing License, 2011 to present
Montana State Registered Nursing License, 2005 to 2016 (presently inactive)
Utah State Registered Nursing License, 2005 to present
California State Registered Nursing License, 2005 to 2017 (presently inactive)
The United States Department of Labor, Field Nurse Certification, 1999-2001

EDUCATION, ONGOING EDUCATION

Bachelor of Science in Nursing, June 1987 - Oregon Health Sciences University, Portland, OR. *Graduated Highest Honors*
Post Graduate Course Work: 120 hours post graduate course work in life care planning – University of Florida/Intelicus, 2002

HONORS

Sigma Theta Tau, International Honor Society of Nursing, Beta PSI Chapter, 1986-2007
OHSU School of Nursing Scholarship, 1985, 1986, 1987
OHSU The National Dean's list, 1986, 1987

ACTIVITIES PROMOTING THE ADVANCEMENT OF LIFE CARE PLANNING and CERTIFIED CASE MANAGEMENT PRACTICE

2018-present. IARP/IALCP Section Board of Directors; Member-at-Large (International Association of Rehabilitation Professionals/International Academy of Life Care Planning)

2018-present. IALCP 2019 International Academy of Life Care Planning Symposium Committee: Member

2018-present. IARP Education Committee; Member

2018-present. IARP Logistics Education Subcommittee; Chair

2018-present. IARP Legislative Affairs Committee; IALCP Section Representative

2017-present . Commission for Case Manager Certification (CCMC) Item Development Project; Participant. Assist with writing and researching foundation for Certified Case Management certification examination questions (item writing) and ongoing revision of items progressing through testing, evaluation and finalization phases examination preparation.

2017 Life Care Planning Summit; Summit Participant & Nominal Process Volunteer
2017 Life Care Planning Post-Summit Committee; Member. Content contributor to summit recommendations focused on costs, collateral sources and life care planning. Summit proceedings published: Albee T., Gamez J., Johnson C. 2017 Life Care Planning Summit Proceedings, *Journal of Life Care Planning,* 15(3), 19-29).

2013-2014 Participated in Standards of Practice for Life Care Planners, Life Care Plan Practice Survey which reviewed Life Care Plan Standards, offered suggestions and recommendations to Standards of Practice Committee for inclusion in revised Life Care Plan Standards of Practice. Participated in review of Draft Standards of Practice for Life Care Planners, offered comments and recommendations for additional revision.

2006 Life Care Planning Summit; Participant and Content Contributor to published summit recommendations focused on continuing education, professional development, peer review, and growth in field. Summit proceedings published: Riddick-Grisham, S. BA, RN, CCM, CLCP, editor 2006 Life Care Planning Summit Proceedings, *Journal of Life Care Planning,* 5 (3), 57-90.

2004 Life Care Planning Summit; Participant and Content Contributor to published summit recommendations focus areas of certification process, CLCP examination and CEU credits, future research in Life Care Planning, CLCP mentoring program, and Standards of Practice for Life Care Planners. Proceedings published: Deutsch, P., editor (2004) Life Care Planning Summit 2004, *Journal of Life Care Planning,* 3 (2), 193-202.

2002 Life Care Planning Summit; Participant and Content Contributor to published summit recommendations focus areas of Life Care Plan methodology/functions, professional development, ethics, and the future of Life Care Planning. Proceedings published: Riddick-Grisham, S. RN, BSN, CCM, CLCP, editor (2003) Life Care Planning Summit 2002, *Journal of Life Care Planning,* 2 (2), 57-140.

LECTURES and PRESENTATIONS

17th Annual Pacific Northwest Brain Injury Conference 2019
"Impact of Life Care Planning and Catastrophic Case Management after Brain Injury, Stroke or Neurological Changes"
Dana Penilton, Portland, Oregon 3-8-19

17th Annual Pacific Northwest Brain Injury Conference 2019
"Medical Marijuana (Cannabidiol-CBD) as a Potential Adjunct Treatment Modality"
Dana Penilton, Portland, Oregon 3-9-19

International Association of Rehabilitation Professionals Annual Conference/ International Symposium on Life Care Planning
"Consideration of Medical Marijuana Inclusion in Life Care Planning: Implications and Challenges"
Dana Penilton and Tracy Albee, Charlotte, North Carolina. 10-27-18

International Association of Rehabilitation Professionals Annual Conference / 23rd Annual International Symposium on Life Care Planning
"Price, Cost, Charge, Payment: Life Care Planning Conundrum"
Dana Penilton and Karen Preston, St. Louis, Missouri. 10-14-17

Pacific University College of Optometry, guest lecturer at invitation of Hannu Laukkanen OD, Pacific University Clinical Professor of Optometry and Chief of Vision Therapy Services
"Catastrophic Medical Case Management and Life Care Planning after Brain Injury"
Dana Penilton, Forest Grove, Oregon. 6-30-17

Pacific University College of Optometry, guest lecturer at invitation of Hannu Laukkanen OD, Pacific University Clinical Professor of Optometry and Chief of Vision Therapy Services
"Catastrophic Medical Case Management and Life Care Planning after Brain Injury"
Dana Penilton, Forest Grove, Oregon. 6-21-16

International Association of Rehabilitation Professionals Annual Conference/International Symposium on Life Care Planning
"Spinal Cord Injury: Life Care Planning Approaches and Considerations"
Dana Penilton and Carol Hadley-Fricks, New Orleans, Louisiana. 10-22-15

Transitions Professional Center Didactic Thursdays
"Patient Advocacy and Collaboration: Thinking Outside the Box"
Dana Penilton, Portland, Oregon. 12-18-14

Life Care Planning Summit, National Meeting; Panel Presenter
"Life Care Planning; New Markets and Maintaining Referrals"
Dana Penilton, Chicago, Illinois. 5-7-06

Oregon Law Institute of Lewis & Clark Law School
"Demystifying Medical Records and Assessing the Use of Life Care Plans"
Dana Penilton, Portland, Oregon. 9-30-05, lecture published as noted below.

Council on Education in Management, Regional Meeting
"Strategies to Successfully Manage Workers' Compensation Costs"
Dana Penilton, Portland, Oregon. 1-12-05

ParadigmHealth Corporation, Regional Meeting
"Avoiding Pitfalls- Transitioning a Case from One Network Manager to Another"
Dana Penilton, Las Vegas, Nevada. 9-14-04.
Lecture also presented via National Internet Teleconference on 9-30-04 and available to Paradigm Network Managers as ongoing independent internet study course.

Care Medical Rehabilitation Sales Annual Meeting, Keynote Speaker
"Collaboration between Medical Case Managers and Rehabilitation Consultants"
Dana Penilton, Portland, Oregon. 5-7-03

Insurer and Third Party Administrator Claims Adjusters
"Occupational Knee Injuries"
Dana Penilton, Salem, Oregon. 1997 & 1998

SAIF Adjusters
"Medical Providers Can Be Your Ally"
Dana Penilton, Salem, Oregon. 1994, 1995, 1996

SAIF Investigators
"Taking a Medical History"
Dana Penilton, Salem, Oregon. 1996

SAIF Employees
"Managed Care Organization Tools & Procedures"
Dana Penilton, Salem, Oregon. 1995, 1996

SAIF Nurse Consultant Team, Spinal Cord Injury Team
"Baclofen Pump Use: Medical Indications & Management"
Dana Penilton, Salem, Oregon. 1995

SAIF Employees Medical Education Series
"Spinal Cord Injury" - 1994, 1995
"Cardiac Disease & Medical Management" -1994, 1995
Dana Penilton, Salem, Oregon.

Northwest Occupational Health Conference
Outcomes in Workers' Compensation: SAIF/CROET (Research of Occupational and Environmental Toxicology Outcomes Research Project "Preliminary Research Findings"
Dana Penilton, Seaside, Oregon. 1994

SAIF Policy Holders Seminar
"On the Front Line with Back Injuries"
Dana Penilton, Portland, Oregon. 1994

Marion Polk County Medical Society
"SAIF: Who are We?"
Dana Penilton, Salem, Oregon. 1994

SAIF Employees
"Carpal Tunnel Syndrome in Workers' Compensation"
Dana Penilton, Salem, Oregon. 1994

SAIF Investigators
"Cardiac Disease Training"
Dana Penilton, Salem, Oregon. 1994

Linfield College, School of Nursing: Sigma Theta Tau Chapter
"Entering Critical Care Nursing as a New Graduate"
Dana Penilton, Portland, Oregon. 1988

PUBLICATIONS and POLICY & PROCEDURE DEVELOPMENT IN FIELD
Authored/Co-Authored:

Masterson J., Woodard L., Mitchell N., Penilton D., Smolarski R., Mertes A., Marcinko D., Thomas K., Turner D. (2019). International Academy of Life Care Planners' position paper on transdisciplinary practice. *Journal of Life Care Planning.* 17 (2): 3-4.

Penilton, Dana RN, BSN, CCM, CLCP. (2006) Avoiding Pitfalls-Transitioning a Case from One Network Manger to Another, *Paradigm Corporation Internet Website available to Paradigm Corporation Nurses across the Nation.*

Penilton, D.RN, BSN, CCM, CLCP (2005) *Demystifying Medical Records and Assessing the Use of Life Care Plans, Chapter Three.* Presenting and Defending Medical Issues in Personal Injury Cases. Oregon Law Institute, Lewis & Clark Law School.

Riddick-Grisham, S. RN, BSN, CCM, CLCP & Penilton, D. RN, BSN, CCM, CLCP (2005) Lifetime Medical Cost Projections Do Not Equal Life Care Plan*, LNC Resource: The National Source for Legal Nurse Consulting* 2 (6), 1 and 22-23.

Penilton, D. RN, BSN, CCM, CLCP (Winter 2005) Facilitation of Case Manager Transition*, Oregon Medical Case Management Newsletter*, Oregon Chapter of Case Management Society of America

Penilton, D. RN, BSN, CCM; Bertram B. MD; Wilson, C. RN, CCM (1998) *ODS Health Plan Integrated Health Care Policies and Procedures Manual*, Oregon Dental Association Health Plans

Penilton, D. RN, BSN, CCM contributing author (1998) *ODS Health Plan: Plan 24 Physician Manual*, Oregon Dental Association Health Plans

Penilton, D. RN, BSN, CCM (1997) *Occupational Knee Injury Instruction and Resource Manual*

Penilton, D. RN, BSN, CCM contributing author (1996) *Managed Care Organization Training Modules,* SAIF Corporation,

Penilton, D. RN, BSN, CCM- primary author (1996) *Vehicle Modification Policy & Procedure,* SAIF Corporation

Penilton, D. RN, BSN, CCM- primary author (1996) *Home Modification Policy & Procedure,* SAIF Corporation

Penilton, D. RN, BSN, CCM- primary author (1996) *Supplemental Allowance Policy & Procedure,* SAIF Corporation

Penilton, D. RN, BSN, CCM (1995) Chapter 4 Cardiac Disease *Medical Education Series Training Manual,* SAIF Corporation

Penilton, D. RN, BSN, CCM- quoted: (January 1995) *Case Management Advisor* 6 (1). Family Support Boosts Rehab Potential and Caring For Caregivers: Families Need a Break

Penilton, D. RN, BSN, CCM- contributing author (1994) *Northwest Pharmacy Services Managed Care Training Manual*, SAIF Corporation

Penilton, D. RN, BSN, CCM- quoted: (December 1994) *Case Management Advisor,* 5, (12). Integrated Care Reduces Costs, Gives Case Management a Boost*,* December 1994, vol. 5, no. 12.

Penilton, D. RN, BSN, CCM- contributing author (1994) *Medical Condition Classification System,* SAIF Corporation

Penilton, D. RN, BSN-contributing author (1990) *Hyperbaric Oxygen Therapy Policies & Procedures,* Providence Medical Center

Penilton, D. RN, BSN-contributing author (1990) *Critical Care Standards of Care,* Providence Medical Center

Penilton, D. RN, BSN-contributing author (1998) *Critical Care Policies & Procedures,* Providence Medical Center

Penilton, D. RN, BSN- Co-author chapter 7(November 1988) Using Nursing Research Christine Tanner PhD, RN, FAAN & Carol Linderman PhD, RN, FAAN editors, *Nursing Care of Adults,* , National League for Nursing

PROFESSIONAL EXPERIENCE

Dana Penilton Consulting, Inc.
Owner/President: Certified Life Care Planner, Nurse Consultant, Certified Medical Case Manager specializing in catastrophic medical management
June1998 to present

Life Care Planning and coordination of care and medical case management services with specialty in catastrophic injury management (brain injury, spinal cord injury, burn injury, multiple trauma, amputation, pediatric, etc.). Medical management focuses on the development and implementation of individualized rehabilitation plans to maximize function, coordinate return to the highest level of function, return to community and if possible return to volunteer, partial employment, or gainful employment.

Life Care Planning is a tool utilized to identify and quantify future medical needs and associated costs over the lifetime of a person who has sustained a catastrophic injury or chronic condition. Life Care Plan work is completed for both plaintiff and defense counsel.

Other services have included coordination of benefits, development of systematic and customized approach to facilitate rehabilitation for complex medical situations, as well as mentoring colleagues in catastrophic case management and life care planning. These services are available to patients, families, attorneys, trust officers, claims adjusters, insurers, third party administrators, and self-insured employers.

In collaboration with two colleagues created and implemented procedures and processes for Integrated Health Care Product; a 24 hour product that covered group health and workers' compensation injuries and illnesses for Oregon Dental Association (ODS).

Provided Managed Care Organizational (MCO) administration, MCO nurse case management services and coordinated multi-disciplinary team cohesiveness to promote successful patient outcomes for ODS, Caremark/Oregon Health Systems and MedOptions Care Management Resources.

Creative Medical Concepts Consortium, Inc.
Co-Owner: Nurse Consultant/Certified Case Manager/Life Care Planner
August 1997 to June 1998. June 1998 the company restructured to Dana Penilton Consulting, Inc.

The Medical Resource Network, Inc.
Nurse Consultant/Certified Case Manager/Life Care Planner
August 1996 to August 1997

Developed, implemented and marketed a workers' compensation case management program as well as mentored and trained colleagues in workers' compensation and case management processes and procedures. Provided a broad array of services including medical case management with an emphasis on catastrophic care management, workers' compensation injuries, life care planning, cost benefit

analysis, return to work coordination, and work site evaluations. Developed program for and implemented life care planning services and participated in development and implementation of an elder care program.

SAIF Corporation (State Accident Insurance Fund, Oregon)
Nurse Consultant
April 1990 to August 1996

Collaborated and provided nurse consultation serves with injured workers, medical providers, claims adjusters, and attorneys in all aspects of workers' compensation claims management. Participated in advancement and implementation of medical case management programs as well as creation and development of policies and procedures and associated team training. Primarily provided life care planning and comprehensive medical case management services for catastrophic, spinal cord injured, traumatic brain injured, and multiple catastrophic diagnoses of disabled workers although additionally assisted with less severe injured workers with complex claims issues. Interacted and worked extensively with managed care organizations. Assisted in development and implementation of Northwest Pharmacy Service Network (NWPSN) program. Participated in Center for Research of Occupational and Environmental Toxicology (CROET) Outcomes Research Project and data collection as well as co-presenting CROET's initial research findings at the 1994 Annual Northwest Occupational Health Conference. Presented lectures to SAIF employees and SAIF policyholders.

Al Miller & Associates
Independent Nurse Contractor- Critical care nursing in Intensive Care Units
December 1989 to April 1990

Worked as an independent nurse contractor and practiced critical care nursing at several Portland area and coastal Oregon hospitals.

Providence Medical Center
Staff Nurse: Coronary Care Unit & floated to Intensive Care Unit and Hyperbaric Unit
June 1987 to April 1990

Provided nursing in the Coronary Care Unit (CCU) and served as float nurse to Intensive Care Unit (ICU) and Hyperbaric Unit (HBO-U). Responsibilities included providing nursing care to critically ill medical and surgical cardiac patients, open-heart surgery recovery, critically ill medical-surgical patients, and provision of hyperbaric treatments for chronically, acutely and critically ill patients. Demonstrated leadership by actively participating and serving on ICU Charting Committee, CCU Policy and Procedures Committee, HBO-U Policy and Procedures Committee, CCU Standards of Care Committee, HBO-U Charting Committee and CCU Education Committee.

LEADERSHIP, PROFESSIONAL AFFILIATIONS and PROFESSIONAL ADVANCEMENT ACTIVITIES

2018-present	IARP (International Association of Rehabilitation Professionals) Life Care Planning/IALCP (International Academy of Life Care Planners) Section, Member-At-Large, *Board Member*

2018-present	IARP (International Association of Rehabilitation Professionals) IARP Education Committee, Member & Education Logistics Subcommittee, *Chair*
2018-present	IALCP (International Academy of Life Care Planners) Symposium Planning Committee, *Member*
2018-present	IARP (International Association of Rehabilitation Professionals) Legislative Affairs Committee, *Life Care Planning Section Representative*
2017-present	Brain Injury Connections-Northwest; *Secretary, Executive Board Member*
2017-present	CCMC (Commission for Case Manager Certification) Certification Examination Item Development Project, *Member*
1999-present	Case Management Society of America, *Member* Oregon Medical Case Managers Group; *previously served as local chapter President, Immediate Past President, Vice President, Secretary and Conference Planning Committee*
1999-present	International Association of Rehabilitation Professionals-International Academy of Life Care Planners, *Member Life Care Planning Section (previously under Forensic Section)*
1998-present	Brain Injury Alliance of Oregon, chapter of Brain Injury Association of America (previously Brain Injury Association of Oregon), Portland Chapter, *Member. Previously Vice President, Board Member, Conference Planning Committee and Advisory Board Member*
2006-2014	North American Brain Injury Society (NABIS), *Member*
2004-2015	American Association of Spinal Cord Injury Nurses, *Member*
2004-2010	Northwest Occupational Medicine Center (outpatient multi-disciplinary pain management treatment program), *Advisory Board Member*
1998-2000	Homeward Bound Rehabilitation Service, *Advisory Board Member*
1997-2000	Professionals in Workers' Compensation, *Member*
1996-2000	State Board of Nursing Outcomes Committee, *Appointment*
1988-2007	Sigma Theta Tau International, The Honor Society of Nursing, *inducted 1988. Served on Public Relations Committee 1988*

1997	Washington Self Insured Association, *Corporate Membership*
1996-1998	American Association of Legal Nurse Consultants, *Member*
1996- 1997	Oregon Self Insured Association, *Corporate Membership*
1995	Independent Case Management Association (Merged with Case Management Society of America in 1996), *Member*
1995-1996	SAIF Corporation: Traumatic Brain Injury Team, *Chair & Member*
1995-1997	SAIF Corporation: Nursing Case Management Policy Development Committee, *Member*
1994	SAIF Corporation: Appellate Review/Board Review Committee, *Member*
1994	SAIF Corporation: Medical Case Management Project, *Facilitator*
1994-1996	SAIF Corporation: Home/Vehicle Modification and Supplemental Allowance Policy & Procedure Development Committee, *Team Leader*
1994-1996	SAIF Corporation: Northwest Pharmacy Services Committee Program Development & Implementation Committee, *Member*
1993-1997	American Association Rehabilitation Nurses, *Member*
1991-1996	SAIF Corporation: Cardiac Advisory Committee, *Co-Chair*
1991-1995	SAIF Corporation: Spinal Cord Injury Team, *Chair & Member*
1987-1990	Providence Medical Center, member of ICU Charting Committee, member of CCU Policy and Procedures Committee, member of HBO-U Policy and Procedures Committee, member of CCU Standards of Care Committee, member of HBO-U Charting Committee and member of CCU Education Committee
1987-1996	American Association of Critical Care Nurses, *Member*
1984-1987	OHSU School of Nursing Undergraduate Council, School of Nursing Grievance Committee, and Nursing Student Senate, *Member*
1984-1987	Oregon Health and Sciences University, School of nursing; tutor biochemistry, anatomy and physiology

COMMUNITY VOLUNTEER ACTIVITIES/HOBBIES

1994-1998	Site Counsel, Rieke Elementary School; participated in development of school curriculum
1994-1999	Volunteer at Rieke Elementary School; participated in teacher assistant activities, tutoring children, assisting with reading program and library volunteer
2005-2007	Habitat for Humanity; participated in Woman Build Projects, assisted in building one single dwelling, one duplex unit, and fundraising activities
2005, 2006	National Center for Sports Center for Disabled; participated in soccer camps for children multiple types of disabilities
2012, 2018	Portland-Kaohsiung Sister City Association, volunteer at Portland Dragon Boat Races
2013-present	Dragon Boat Paddling Team
2014, 2016	Wounded Warrior Project, organized and participated in Tough Mudder team, fundraising for Wounded Warrior Project
2015-2016	Returning Veterans Project, volunteer
2017-present	Brain Injury Connections NW, Executive Board Member-Secretary

Hobbies include; hiking, yoga, snowshoeing, paddling on a dragon boat team, camping, knitting, gardening and playing with my puppy.

Dana Penilton RN, BSN, CCM, CLCP
Certified Life Care Planner
Certified Case Manager

Federal Rules of Evidence 26 (2)(a)(B) Disclosure

Publications (partial):

- ✓ Penilton, D. Demystifying Medical Records and Assessing the Use of Life Care Plans, Chapter Three. *Presenting and Defending Medical Issues in Personal Injury Cases.* Oregon Law Institute, Lewis & Clark Law School. 2005.
- ✓ Riddick-Grisham, S. and Penilton, D. (2005) Lifetime Medical Cost Projections do not equal Life Care Plan, *LNC Resource: The National Source for Legal Nurse Consulting* 2 (6), 1 and 22-23.
- ✓ Penilton, D. (Winter 2005) Facilitation of Case Manager Transition, *Oregon Medical Case Management Newsletter*, Oregon Chapter of Case Management Society of America.
- ✓ Penilton D. Co-author Chapter 7, Tanner C. & Lindeman C, editor (1988) *Nursing Care of Adults*, Using Nursing Research. National League for Nursing.

Fees:
Life care planning time $225.00 per hour
Research assistant time $125.00 per /hour
Trial/Deposition testimony time $275.00 per hour

Case	Plaintiff Attorney	Defense Attorney	Title of Case	Deposition	Trial Date	Venue	Outcome
No. 14-2-21714-5 SEA	Retained by Heather Jenson LEWIS BRISBOIS BISGAARD & SMITH LLP	Joseph P. Lawrence Jr. LAWRENCE LAW GROUP LLC	Joslyn Paulson v. LCS Westminster Partnership 3 LLP, DBA Timber Ridge at Talus	5-1-15		Superior Court of Washington For King County	Case Settled

Case	Plaintiff Attorney	Defense Attorney	Title of Case	Deposition	Trial Date	Venue	Outcome
No. 3PA-13-2561	Retained by Curtis Martin LAW OFFICES OF CURTIS W. MARTIN	Rebecca A. Lindemann LAW OFFICES RICHMOND & QUINN Paul Stockler LAW OFFICE OF PAUL D. STOCKLER	Larry Hill v. Michael Martin, First Student, Inc. and Guidry Enterprise, Inc. and DOES 1-10 inclusive	8-17-15		Superior Court for the State of Alaska	Case Settled
No: 14CV07336	Retained by Anthony Petru HILDEBRAND McLEOD & NELSON LLP	Timothy J. Coleman, COSGRAVE VERGEER KESTER LLP	James Dorrance v. Union Pacific Railroad Company		3-29-16	Multnomah County Circuit Court, Case	Jury Verdict
No: 2:15-CV-01957-SU	Retained by Keith Tichenor TICHENOR & DZIUBA LLP	John Hart Karen O'Kasey HART WAGNER LLP	Cassi C. Fisher as Guardian ad Litem for X.S.F., a minor v. Winding Waters Clinic, PC, an Oregon Corporation; Elizabeth Powers, MD; Keith DeYoung MD; and Renee Grandi MD	2-21-17		United States District Court for District of Oregon, Pendleton Division	Case Settled
No: 16 CV37586	Retained by Kathryn Reynolds Morton LAW OFFICE OF KATHRYN REYNOLDS MORTON	Derek Johnson Jennifer Middleton JOHNSON JOHNSON LUCAS & MIDDLETON	Stuart Wagner, Plaintiff v. Brewer & Brewer, Inc., an Oregon Corporation and Lavon Bagwell, an individual, Defendants		3-1-18	Lane County Circuit Court	Jury Verdict

Case	Plaintiff Attorney	Defense Attorney	Title of Case	Deposition	Trial Date	Venue	Outcome
No. 15-2-28905-5 SEA	Karen Koehler THE STRITMATTER FIRM, KESSLER KOEHLER MOORE	Retained by Scott Wakefield FALLON McKINLEY & WAKEFIELD PLLC Vanessa Lee SEATTLE CITY ATTORNEY'S OFFICE Patricia Buchanan PATTERSON BUCHANAN FOBES & LEITCH INC. Patricia Todd WASHINGTON STATE OFFICE of ATTORNEY GENERAL	Phuong Dinh; Mazda Hutapea; Yuta Masumoto; Yu Zhuang; Gunter Zielinski; Fenna Zielinski; Terry Sheldon; Richard Sheldon; Ronald Sheldon; Kathleen Sheldon; Rhonda Cooley; and Joanne Gerke, (known collectively as the "Dinh Plaintiff Group"), Plaintiffs v. Ride the Ducks International, LLC, a foreign Company; tide the Ducks of Seattle, LLC, a Washington Company; Eric Bishop and Jane Doe Bishop, and their marital community; State of Washington; City of Seattle, Defendants		1-4-19	Superior Court of Washington for King County	Jury Verdict

Dana Penilton Consulting, Inc.

6312 SW Capitol Hwy.
#418
Portland, OR 97239-1937

cell [redacted]
fax [redacted]
danapen@comcast.net

www.danapenilton.com

Fee Schedule
Tax ID # 93-1243583

Service Coverage Area

- National
- International

Life Care Planning Fees

- Life Care Plan Preparation: $225.00 per hour
    - Deposition Testimony: $275.00 per hour: Estimate of professional time to be paid in advance of testimony, 5 hour minimum. Prepaid testimony fee will be reimbursed with 10 business day cancellation notification.
    - Trial Testimony: $275.00 per hour: Estimate of professional time to be paid in advance of testimony, 3 hour minimum. Prepaid testimony fee will be reimbursed with 10 business day cancellation notification.
- Research Assistant: $125.00 per hour
- Billing of Services: 6 minute increments
- $2,500.00 retainer fee which will be credited toward professional services rendered on first invoice. After the retainer if fully applied, periodic statements will be sent for ongoing services rendered.

Medical Case Management Fees

- Medical Case Management Services: $125.00 per hour

Dana Penilton RN, BSN, CCM, CLCP
Certified Life Care Planner
Certified Medical Case Manager